UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

THE HIDGANED COMPANY INC)
THE HIPSAVER COMPANY, INC., Plaintiff / Counterclaim Defendant,)
Tament / Councierann Defendant,)
v) Civil Action No. 05-10917 PB:
)
J.T. POSEY COMPANY,)
Defendant / Counterclaim Plaintiff.)
)
)

EXHIBITS

TO HIPSAVER'S OPPOSITION TO DEFENDANT J.T. POSEY COMPANY'S MOTION FOR SUMMARY JUDGMENT ON PLAINTIFF'S COMPLAINT [D.N. 179] & HIPSAVER'S OPPOSITION TO DEFENDANT J.T. POSEY COMPANY'S MOTION FOR PARTIAL SUMMARY JUDGMENT ON ITS **COUNTERCLAIM [D.N. 180]**

THE HIPSAVER COMPANY, INC. By its Attorneys,

/s/ Courtney M. Quish

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January 8, 2007

CERTIFICATE OF SERVICE

I certify that this document has been filed through the Electronic Case Filing System of the United States District Court for the District of Massachusetts and will be served electronically by the court to the Registered Participants identified in the Notice of Electronic filing.

/s/ Courtney M. Quish January 8, 2007

EXHIBIT 1

Opposition Exhibit 1: Disputed Facts

Fact Number	Posey's Claim	Posey's Support	HipSaver's Dispute of the Claim	HipSaver's Support
5.	A hip protector is generally a protective device that covers the hip and is intended to help prevent hip fractures in elderly persons caused by falls.	Lewis Decl., ¶ 3.	Posey has no evidence that its product covers the hip. In fact, in validation testing in the UK by Minns and associates, it has been determined that Posey's product fails to cover the hip.	Opposition Exh . 26, Sept. 8, 2005, Correspondence from Prof. Minns to Posey Co.
12.	Posey's advertising materials that made reference to the Garwood testing were disseminated continually from late 2001 until 2005.	Lewis Decl., ¶ 8.	Posey withdrew its Garwood ads in the fall of 2003 when it launched its UCLA White Paper advertising. The Garwood advertising was not continuous. Posey revived the Garwood ads in the fall of 2004, shortly after settlement of the 2004 Litigation in which HipSaver challenged the UCLA White Paper advertising.	Opposition Exh. 2, Goodwin Decl. at ¶¶ 23, 24; Opposition Exh. 5, Posey UCLA ads
13.	HipSaver's president, Goodwin, learned at least as early as 2002 that Posey was using the results of the Garwood testing in its advertising.	Goodwin Depo., Oct. 18, 2005, at 43:5	Although HipSaver learned of the initial Garwood advertising in 2002 and 2003, Mr. Goodwin dismissed the advertising as junk science. He was not aware of the national scope of this advertising. He was not aware that Posey had made comparison claims of superiority directly to the Veterans Administration in July 2001, and he was not	Opposition Exh. 2, Goodwin Decl. at ¶¶ 11, 12; Opposition Exh. 7, Goodwin Depo. Oct. 18, 2005 at 69:14- 70:8

Fact Number	Posey's Claim	Posey's Support	HipSaver's Dispute of the Claim	HipSaver's Support
			aware of similar claims made in a Posey advertising video.	
15.	In approximately late-2003 or early 2004, Posey disseminated some advertising that made reference to some testing results that were reported in a so-called "White Paper."	Morseburg Decl., ¶ 2; Posey Decl., ¶ 3.	For eleven months beginning in the late fall of 2003, Posey pursued a nationwide false advertising campaign based on its literally false UCLA White Paper. Posey admitted that its advertising could not be supported by any reliable research and withdrew the advertising as part of a settlement of the 2004 Litigation.	Opposition Exh . 10, Special Announcement; Opposition Exh . 11, Settlement Agreement
17.	The gist of HipSaver's complaint in Posey I was that Posey was using false and misleading advertising in an effort to drive HipSaver from business.	Morseburg Decl., ¶ 4; Exh. 1.	The Complaint filed by HipSaver in 2004 challenged the UCLA White Paper ads as unequivocally stated in the corrective advertising statement and Settlement Agreement. The Complaint did not challenge the Garwood ads which had been	Opposition Exh . 10, Special Announcement; Opposition Exh . 11, Settlement Agreement;
18.	In connection with its claims in Posey I, HipSaver sought, among other things, damages and preliminary and permanent injunctive relief preventing Posey from publishing any statements that made reference to the superiority of its hip protection products over HipSaver's hip protection products.	Morseburg Decl., ¶ 4; Exh. I .	withdrawn by Posey in the fall of 2003. Mr. Goodwin thought the Garwood ads had been withdrawn permanently.	Opposition Exh . 2, Goodwin Decl. at ¶¶ 23, 24, 26

Fact Number	Posey's Claim	Posey's Support	HipSaver's Dispute of the Claim	HipSaver's Support
21.	When the parties settled Posey I, they intended that, in the absence of any material changes in the facts or circumstances that existed at the time, the settlement would permit the continued publication and dissemination by each of them of advertisements and commercial statements that had been published and disseminated in hard copy or electronically prior to the execution of the Settlement Agreement. They also intended that claims by either of them against the other based upon the republication or dissemination of advertisements or commercial statements that were the same as, or substantially similar to, any such earlier statements would be barred.	Posey Decl., ¶ 4	HipSaver understood that the Settlement Agreement applied to the claims and counterclaims at issue in the 2004 Litigation. Mr. Goodwin understood that the Settlement Agreement barred any further claims by HipSaver against the UCLA ads in return for withdrawal of those ads and corrective advertising. The Settlement Agreement does not apply to claims which were not asserted or could not have been asserted in 2004.	Opposition Exh. 2, Goodwin Decl. at ¶¶ 24, 27; Opposition Exh. 11, Settlement Agreement; Opposition Exh. 7, Goodwin Depo., Oct. 18, 2005, at 47:14- 48:11, 51:24-54:3
23.	The gravamen of HipSaver's complaint in this case is exactly the same as it was in Posey I, which is that Posey is using false and misleading advertising in an effort to drive HipSaver from business.	Morseburg Decl., ¶ 8; see generally FAC, at p. 1 (Docket No. 66).	The Complaint in the present lawsuit challenges the revived Garwood advertising campaign. The 2004 Litigation challenged the UCLA White Paper ads.	Opposition Exh . 2, Goodwin Decl. at ¶¶ 30-32; Opposition Exh . 7, Goodwin Depo., Oct. 18, 2005, 153:6-54:5

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24.	In response to HipSaver's letter Posey subsequently revised the "Garwood language" in its advertisements in May 2005.	Lewis Decl., ¶ 9; compare Exhs. 19, 20, 21 and 22 with Exh. 23.	Posey launched the revived Garwood advertisements during the fall of 2004, shortly after the settlement of the 2004 Litigation and did not make any material changes to the revived ads in response to HipSaver's demand letter. After its motion to dismiss this lawsuit was denied, Posey withdrew the revived Garwood ads.	Opposition Exh. 2, Goodwin Decl. at ¶ 32; Order Denying Motion to Dismiss [D.N. 4]
26.	The language in the ad to which HipSaver objected on May 3, 2005 which concerns the Garwood testing is virtually identical to the language concerning the Garwood testing that was contained in Posey advertisements that had been disseminated prior to the execution of the Settlement Agreement.	Lewis Decl., ¶ 6; compare Exhs. 19, 20 and 21 with Exh. 22.	Posey mischaracterizes the revived Garwood Ads. The 2004/2005 ads make effectiveness and launderability claims about a new product, Posey's so-called High Durability hip protector, as well as Posey's 2001 hip protection product. The new product was not mentioned in Posey's 2001 Garwood ads. Further, the revived ads were not limited to the 2001 testing but incorporated new testing conducted in 2004 and early 2005.	Opposition Exh . 6, revived Posey Garwood ad; Opposition Exh . 7, Goodwin Depo., Oct. 18, 2005, at 238:21- 239:10
29.	HipSaver subsequently amended its complaint to state a claim for product disparagement. The claim is based upon a single email communication from a former Posey employee to several individuals who worked at a	Morseburg Decl., ¶ 10; Yates Decl., ¶12-8 and Exhibits "A" and "B"	Posey's mischaracterizes its literally false advertising to the Veterans Health Administration. This false advertising was sent to at least three Veterans Health Administration health care facility sites. HipSaver learned of this advertising only as	Opposition Exh . 4; Opposition Exh . 2, Goodwin Decl. at ¶ 11; Opposition Exh .

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	VA hospital in Los Angeles and which may have been accompanied by a chart which made reference to the Garwood testing.	thereto	a consequence of discovery in this lawsuit.	7, Goodwin Depo., Oct. 18, 2005, at 60:7- 61:13
30.	During discovery, HipSaver was unable to identify any damages it suffered as a consequence of any of the acts alleged in the Complaint.	See Goodwin Depo., Oct. 18, 2006, at 60:7-62:24, 86:21-24, 140:19-23, 141:1-12, 148:12- 152:12, 156:2-157:5; Goodwin Depo., Nov. 30, 2006, at 23:2-24:6; Suppl. Response to Interrog. No. 2.	HipSaver has lost accounts. HipSaver has been frozen out of every major distributor and health care facility chain in the United States. HipSaver is left today with less than half of the U.S. marketplace. HipSaver's rate of growth is less than half of Posey's rate of growth. HipSaver's rate of growth is declining, and revenue is flat. More than 40% of HipSaver's business and all of its growth is accounted for by a single client, the Veterans Health Administration. Significantly, the Veterans Health administration is the only large client which is largely immune to false advertising because it conducts independent clinical evaluations of products.	Opposition Exh. 19, Expert Report of Roy J. Epstein, PhD; Opposition Exh. 2, Goodwin Decl. at ¶¶ 2, 13-19, 32; Opposition Exh. 7, Goodwin Depo., Oct. 18, 2005, at 141- 145:3, 148:23- 149:5, 151:16- 152:12

Fact Number	Posey's Claim	Posey's Support	HipSaver's Dispute of the Claim	HipSaver's Support
31.	HipSaver was also unable to identify anyone who has purchased Posey's products as a consequence of the Garwood advertising or any customers of its own who have ever ceased buying its products as a result of the Garwood advertising.	Goodwin Depo., Oct. 18, 2005, at 86:21-24, 137:14-20; Goodwin Depo., Nov. 30, 2005, 22:22- 24, 23:2-24:6.	HipSaver has identified major distributors and health care facility chains and independent facilities that have refused to deal with HipSaver because of Posey's actions, including Posey's misrepresentations of the durability and launderability of its products and misrepresentation of the earlier settlement.	Opposition Exh . 2, Goodwin Decl. at ¶¶ 9, 11-21, 29, 32
32.	Posey's damages expert has concluded that HipSaver has suffered no damages as a consequence of the Garwood advertising.	Green Decl. & Exhs. "A" & "B" thereto (filed under seal).	HipSaver's damages expert, Roy J. Epstein, PhD, has determined that Posey has employed a "fundamentally misleading and invalid" regression analysis in an attempt to negate a lost profits damages claim by HipSaver. Using a valid methodology, Dr. Epstein calculated damages in excess of \$1.5 million. Moreover, Dr. Epstein has determined that HipSaver has evidence of actual damages based at least in HipSaver's strikingly depressed rate of growth relative to Posey. <i>See also</i> nos. 30, 31 above.	Opposition Exh . 19, Expert Report of Roy J. Epstein, PhD; See also nos. 30, 31 above

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33.	Posey's marketing expert, Gary Reich, has determined that the Garwood advertising at issue would not have affected Posey's sales.	Morseburg Decl., ¶ 11; Exh. 27 (Rule 26 Report of Reich).	HipSaver has filed a Motion to Disqualify Mr. Reich and will press that Motion. Mr. Reich does not have the training, experience, expertise, or data from which to render an expert opinion on the impact of Posey's advertising. The trial court has ruled that Mr. Reich's opinions are disputed and will be resolved at trial.	See HipSaver's Motion to Strike Expert Reports and Testimony of Gary Reich [D.N. 147]; Order, Nov. 15, 2006 re: [D.N. 147]
40.	The "Hip Protectors & the Laundry" page of HipSaver's Internet website also contains a graphic representation that the "wash temperature range" recommended by "CDC Guidelines" is between 160°F and a temperature "somewhere above that."	Piper Decl., ¶ 3; Exh . 14.	On its face, HipSaver's laundry webpage indicates simply that the minimum wash temperature under the CDC Guidelines <i>used</i> by Posey and printed on its products since 2001 was 160°F.	Opposition Exh . 21, Posey hip protector with minimum 160° wash label
44.	HipSaver has never conducted any testing to determine whether its products can be laundered according to the CDC Guidelines.	Brogna Depo, at 20:16- 22:11.	HipSaver and Posey jointly participated in laundry testing conducted independently by the Veterans Health Administration. Testing was initiated in September 2002 at the Mountain Home Veterans Medical	Opposition Exh. 20 at HS2 02205; Opposition Exh. 3; Opposition Exh.
45.	HipSaver has never conducted any testing to determine whether Posey's products or the products of any of its other competitors can be laundered in accordance with the CDC Guidelines.	Brogna Depo., at 23:6-16; Goodwin	Center. HipSaver was represented by Mr. Goodwin and Helen Brogna. Posey was represented by Victoria Lewis. The Medical Center was represented by Randall Nentrup, its Risk Manager and laundry	2, Goodwin Decl. at ¶¶ 20, 22

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		Depo., Oct. 18, 2005, 96:8-16, 99:18-100:18, 105:3-23.	manager. The study coordinator was Eric Stalhanske, Center For Patient Safety. Mr. Stalhanske outlined the study procedures which included laundering in accordance with the high temperature CDC Guideline with washing at 160-170°F, extraction cycle, and drying at 180°F. Ms. Lewis stated that Posey's hip protector product would tolerate the study procedures. HipSaver completed the study without failure. Posey's product had a high rate of failure. Subsequently, the Veterans Health Administration's National Center for Patient Safety issued guidelines for use of hip protectors in which it stated: "As a general rule, Posey TM hip protectors should not be washed in the hospital laundry. They degrade quickly and pads may crack or dissolve. Bleach appears to accelerate the degrading process". The guidelines state also that HipSavers can be washed in hospital laundries without restriction. Since at least the early spring of 2002, less than six months from introduction of the Hipster III product, Posey has been aware that its product is	

Fact Number	Posey's Claim	Posey's Support	HipSaver's Dispute of the Claim	HipSaver's Support
			defective and has a high rate of failure. In fact, notes from an internal Posey meeting to evaluate its defective product in April 2003 indicate that Posey was concerned that it "could lose the market" if it failed to resolve this issue.	
46.	Kevin Minissian, an independent expert hired by Posey, has washed Posey's products according to the CDC's Guidelines. Even after 110 washings, those products are intact.	Morseburg Decl. ¶ 12; Exhs. 25 and 26.	HipSaver contests Mr. Minissian's qualification as an expert, at the very least on the basis that he has misrepresented his graduate education. From his deposition testimony, it is clear that Mr. Minissian does not know if the Posey products were tested in accordance with CDC Guidelines, does not know the substance of whatever laundry test was conducted of Posey products, and did not participate in whatever laundry tests may have been conducted. And notwithstanding specific document requests, Mr. Minissian did not produce a contemporaneous record of whatever wash/bleach/dry protocol may have been employed, did not contemporaneously document the wash/bleach/dry protocol, and has no contemporaneous record of wash/dry temperatures.	Opposition Exh . 22, Minissian Depo. at 20:7-10, 36:7-18, 39:1-40:25, 44:1-51:25

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			His opinion is not grounded in fact or any verifiable evidence and should be rejected.	
49.	HipSaver's statement that the average wash temperature of institution laundries is 180°F is literally false.	Morseburg Decl., ¶ 12; Exh. 25 (Minissian Rule 26 Report).	HipSaver contests Mr. Minissian's qualification as an expert, at the very least on the basis that he has misrepresented his graduate education. Mr. Goodwin has routinely conducted laundry and drying tests of numerous materials. He has tested all of the pads used by HipSaver and all of the pads used by Posey. Further, HipSaver participated in a large scale test by the Veterans Administration. And based on his experience with institutional laundries operated by the VA and a number of private health care facilities and based on temperature readings he has recorded at commercial laundries, the average wash temperature for institutional and commercial laundries is 180°F and is frequently higher. The AIA industry standard for health care facility construction calls for laundry temperatures at 160°F. The CDC high temperature wash guideline is for a minimum temperature of 160°F.	Opposition Exh. 2, Goodwin Decl. at ¶¶ 22, 33; Opposition Exh. 23, CDC Guidelines and reference to AIA standard; Opposition Exh. 7, Goodwin Depo., March 3, 2006, at 45:1-5, 124

Filed 01/08/2007

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			the flawed and misrepresented testing conducted by Posey, HipSaver outperformed Posey's products.	
			77. Posey mischaracterizes the Tampere testing results and engages in a dispute of semantics. Posey's expert, Edward Ebramzadeh, <i>agreed</i> at his deposition that the force reduction can be calculated at 20%, just as represented in the HipSaver website.	Opposition Exh . 17, Ebramzadeh Depo. at 72:2-74:11

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Exhibit 2

Declaration of Edward L. Goodwin

January 8, 2007

- I, **Edward L. Goodwin**, make this Declaration on the basis of personal knowledge and under penalty of perjury.
- 1. I am president of the HipSaver Company. In 1994, I informally surveyed a number of nursing homes and nursing home suppliers. I found that none offered a hip protector to help prevent the 60,000 hip fractures that occurred from falls in the 17,000 nursing homes each year.
- 2. In 1995, I invented the HipSaver® hip protector, a soft foam washable encapsulated protective pad sewn into a garment. I hold a patent for technology related to soft hip protectors, and I have patents pending for related technology. My company has been based in Canton and employs less than 10 people. The HipSaver Company is a privately held company. Revenues from HipSaver were \$1.5 million in 2005 and were flat for 2006.
- 3. Prior to developing HipSaver, I worked as an engineer in the rubber and textile industry for 20 years and thus had the requisite technical background to develop such a product, and I understood and was familiar with equipment and machinery necessary for manufacture.
- 4. Additionally I had worked on new product teams and new product launches and saw the organizational challenges inherent in developing, testing, improving, manufacturing, and selling innovative, high quality products.
- 5. In 1995, I met with Harvard researchers about hip protectors and discussed a variety of topics relating to epidemiology, etiology, hip protector construction, proper pad positioning and biomechanics. Since hip protectors were a new product category, there

was no American Society of Testing and Materials (ASTM) standard to test a hip protector. Therefore, university researchers were constructing a biomechanical test that included all of the known factors in the dynamic fall to the hip. These included soft tissue modeling, trochanteric anatomy modeling, pelvic rebound compliance and literature established fall forces to the hip bone. Such a test could then reveal if a given protective pad could lower the simulated fall force sufficiently to protect the osteoporatic trochanter of an older person. Beginning with testing initiated at Harvard in 1996 through the Tampere testing conducted in 2000 and internal testing conducted since 2004, HipSaver has tested and confirmed the ability of our original and improved hip protector pads to reduce impact forces of a fall. All of HipSaver's testing is verifiable and scientifically simulates a dynamic fall impacting the hip.

- HipSaver is also the subject of a published clinical study directed by a physician 6. at the Fallon Clinic in Worcester. And HipSaver was the subject of one of the first published clinical studies to statistically confirm effectiveness against hip injury which was directed by George Gross, PT, and colleagues at the Elder Service Plan of East Boston. Since 2001, I have invested some \$350,000 in sophisticated manufacturing and test equipment for HipSaver.
- Prior to 2001, HipSaver was practically the only hip protector in substantial 7. distribution to the United States nursing home and rehabilitation hospital market, including the Veterans Administration.
- In 1999, the Posey Company introduced a hip protector product with removable 8. (non-washable) pads. This product did not receive a significant response in the marketplace and was not a competitive threat to HipSaver.

Garwood ads.

- 9. Based on what I have learned in the present lawsuit with the Posey Company, it appears that the Posey Company embarked on an effort to develop a lower cost but inferior copy of our HipSaver product early in 2001. Unknown to us at the time, this development effort included comparative testing of materials, secretive purchase of our products, false claims to our largest customer, the Veterans Administration about the superiority of Posey's new hip protector pad, and development of the 2001 version of the
- 10. Late in 2001, the Posey Company launched its new hip protector product, known as Hipster III. In essence, Posey created in 5 months the "appearance" of a hip protector offering the same benefits that HipSaver had worked on for the previous seven years. It was markedly distinct in appearance from Posey's earlier product, contained what was represented as a washable pad, and looked remarkably like our HipSaver. If you place the two products side by side, it is difficult to distinguish the Posey copy from our HipSaver. In fact, after Posey Hipsters began to fail routinely in health care facility laundries during 2002 and 2003, Posey's products were, on a number of occasions, mistakenly returned to our company – with complaints and demands for refunds.
- 11. Although we learned that Posey had blatantly copied our product and were aware also of its initial Garwood advertising in 2002 and 2003, I dismissed the advertising as junk science. I was not aware of the national scope of this advertising. I was not aware that Posey had made comparison claims of superiority to the Veterans Administration in July 2001, and I was not aware of similar claims made in a Posey advertising video. I was not alarmed by Posey's advertising until its "UCLA" advertising appeared in 2004.

- 12. During 2002 and 2003, I was working to counter Posey's aggressive marketing to the Veterans Administration and its false claims to the VA about the durability and launderability of its hip protector product. Our company was also working very hard to expand sales of HipSaver to nursing and rehab facilities and to obtain agreements with major heath care product distributors and health care chains.
- 13. From 2002 through 2005, our company made numerous efforts to advertise and sell HipSaver to individual nursing and health care facilities, to national chains, and to national distributors.
- 14. HipSaver secured an agreement to be sold by Alimed, a large, Massachusetts based multi-line supplier with national distribution to some 600 nursing and rehab facilities in Massachusetts and about 15,000 across the country. This would have been HipSaver's first opportunity to obtain a vehicle for widespread national distribution. Working with John Bretz, the marketing manager, and his staff we supplied artwork and photos in anticipation of a HipSaver catalog launch during 2002. Mr. Bretz told me that although Alimed had reviewed an earlier Posey hip protector, they wanted to try HipSaver because of its design and testing validation. We built inventory in anticipation the large sales increase, only to be told at the last minute that HipSaver was dropped from Alimed's catalog and replaced by the Posey copy.
- 15. Since then, although we have tried repeatedly, we have been frozen out of all of the major catalog distributors and resellers of hip protectors, including McKesson, Cardinal Health, Medline, and Gulf South which have operations in Massachusetts. Posey is sold by these distributors and resellers. In other cases, one major chain and some facilities have refused to purchase HipSaver because of their experience with

Posey's product. The Posey Hipster failed at high rate in the laundry, customers believed that Posey's advertising misrepresented launderability, and we could not overcome the perception that all hip protector products would fail in the laundry. But, we still pursued the large chains.

- We tried to secure an agreement to supply Manor Care, a major nursing home 16. chain, only to be told by its senior buyer, Bill Cusack, that he would not buy HipSaver because his company had entered into an exclusive arrangement with Posey. Similarly, we worked with Life Care, another national nursing home chain with facilities in Massachusetts, but were rejected by the company's corporate buyer for Posey. And again, in 2003 the corporate purchaser for Kindred, which has a number of health care facilities in Massachusetts, informed us that the company was under exclusive contract with Posey for hip protectors. Recently, we learned that LifeCare Corporation has largely abandoned hip protectors because of the poor quality of Posey's product. LifeCare refused to consider HipSaver as an alternative.
- Numerous individual facilities have also refused to purchase HipSaver. In a 17. number of cases, these facilities have refused to purchase HipSaver hip protectors because of their experience with Posey's product and its repeated failures in the laundry. Included are Bangor Mental Health Institute, Bangor, ME; Truman Medical Center at Lakewood, Kansas City MO; Peaks Care Center, Longmont CO; Dunn County Health Care Center, Menomonie WI; VA Medical Center Bedford, Bedford MA; Resthaven York, York PA; Pleasant Meadows Christian Village, Chrisman IL; Friendship Village, Schaumburg IL; Pisgah Manor, Candler NC; Golden View, Meredith NH; Seneca Place, Verona PA; Phoebe Ministries, Allentown PA; Dow Rummel Village, Sioux Falls SD;

Eaglewood Care Center, Springfield OH; Baptist medical Center, Little Rock AR; Cedar Wood Health Care, Colorado Springs CO; Park River States Care Center, Coon Rapids MN; Regency at the Park, College Place WA; Kennedy Park Medical & Rehab, Schofield WI; River Mede Health Care, Binghamton NY; and Sacred Heart Home, Hyattsville MD.

- 18. Between 2002 and the end of 2005, HipSaver spent almost \$200,000 on advertising primarily to the private market and yielded a total of only 20 nursing homes as customers. We have realized we don't have the capacity to counter Posey's false advertising. By the end of 2005 Posey had captured at least one half of the hip protector market in the United States.
- 19. By the end of 2005, it was clear also that HipSaver has been completely frozen out of every private sector nursing and health care facility chain and every private distribution chain. Our rate of growth in the private marketplace has declined every year since 2002, and we maintain our business largely on the basis of sales to the Veterans Administration which accounts for more than 40% of our U.S. sales and almost all of our growth offsetting other losses in the United States.
- 20. Some of our lost business is due to the fact that the Posey Company's advertising and sale of a defective product has led a number of health care facilities to abandon hip protection products altogether. Since at least the early spring of 2002, less than six months from introduction of the Hipster III product, Posey has been aware that its product is defective and has a high rate of failure. In fact, notes from an internal Posey meeting to evaluate its defective product in April 2003 indicate that Posey was concerned that it "could lose the market" if it failed to resolve this issue. Posey knew early on that

its hip protector failed in institutional laundries but continued to advertise that it could be laundered at high temperature. Some health care facilities have not distinguished between Posey's defective product and our sound product. So, a number of facilities have simply refused to buy any hip protection products.

- 21. When Posey misrepresented the effectiveness and durability and launderability of its product in national campaigns year in and year out, our company simply didn't have the resources or ability to mount a counter campaign. We have been able to maintain most of our business with the Veterans Administration because it is not as susceptible to Posey's advertising. The VA system purchases independently, seeks the best value products, is open to new sources, and conducts its own product evaluation and testing unlike the private sector. Since at least late 2003, our company has spent most of its marketing resources dealing with the VA and fending off Posey's false claims about the superiority, launderability, and effectiveness of its hip protector copy in protecting patients from hip injury.
- 22. HipSaver and Posey jointly participated in laundry testing conducted independently by the Veterans Health Administration. Testing was initiated in September 2002 at the Mountain Home Veterans Medical Center. Helen Brogna and I represented HipSaver. Posey was represented by Victoria Lewis. The Medical Center was represented by Randall Nentrup, its Risk Manager and the laundry manager. The study coordinator was Eric Stalhanske, National Safety Center Manager. Mr. Stalhanske outlined the study procedures which included laundering in accordance with the high temperature CDC Guideline with washing at 160-170°F, extraction cycle, and drying at 180°F. Ms. Lewis stated that Posey's hip protector product would tolerate the study

procedures. HipSaver completed the study without failure. Posey's product had a high rate of failure. Subsequently, the Veterans Health Administration's National Center for Patient Safety issued guidelines for use of hip protectors in which it stated: "As a general rule, Posey™ hip protectors should not be washed in the hospital laundry. They degrade quickly and pads may crack or dissolve. Bleach appears to accelerate the degrading process". In the same guidelines, the Veterans Health Administration notes that HipSaver hip protectors can be washed in hospital laundry facilities without restriction.

- 23. The Posey Company withdrew its first version of the Garwood advertising in the fall of 2003 and blanketed distributors, chains, and facilities with a new campaign, the false UCLA advertising which was distributed in catalogs, newsletters, and mailers, and on the Internet. The UCLA ads were based on a flawed testing protocol conducted by a UCLA graduate student and a white paper which was written or edited by Posey and misrepresented as a "UCLA" study. In this advertising, Posey claimed that its "UCLA" tests demonstrated the superiority of the Posey hip protector over HipSaver. In fact, even though the UCLA tests were flawed, they showed that HipSaver was superior. Nevertheless, Posey utterly misrepresented the tests and embarked on an 11 month campaign against HipSaver.
- 24. In the spring of 2004, HipSaver filed a lawsuit in the federal court in Boston, seeking to halt Posey's false "UCLA" advertising. At the time, the false advertising consisted only of the UCLA ads; there was no Garwood advertising. So, of course, we challenged only what was being advertised at the time. When our company challenged the UCLA ads, we thought Posey had abandoned the Garwood ads for good and, instead, was trying to use the UCLA brand name to attack us.

- Posey filed a "tit for tat" countersuit to our lawsuit in 2004, challenging claims 25. made by HipSaver in our website. After mediation, Posey agreed to a settlement which included withdrawal of all UCLA ads, a corrective advertising statement repudiating the false advertising, payment of attorney fees and associated costs, and dismissal of all claims with prejudice. In conjunction with the settlement, Posey did not request any changes to our website.
- Posey's corrective advertising statement explicitly admitted that UCLA did not 26. sponsor, authorize, or endorse Posey's advertising, that our expert, Wilson C. Hayes, PhD is a recognized biomechanical engineering expert, and that he found that the "UCLA" tests were not reliable and could not sustain "any of the claims" in Posey's advertising. The corrective advertising statement noted Posey's regret at "comparisons with HipSaver products and confusion this may have caused in the marketplace".
- I agreed to the settlement because I thought that corrective advertising would put 27. an end to Posey's false advertising. I understood that the settlement agreement barred any further claims by us against the UCLA ads in return for withdrawal of those ads and corrective advertising, and I understood also that Posey could not challenge our website unless we made material new statements or claims in the website.
- Since the settlement in September 2004, HipSaver has not made any changes to 28. the claims and statements in its website. We have updated several color product photos and added one garment to our HipSaver line, but not so much as a comma has changed in the statements and claims in our website.
- The Posey Company's regret for its false UCLA ads was short lived. I understand 29. that less than a month after the settlement, Posey's president issued a marketing statement

to Manor Care, a 300 facility nursing home chain in which he undercut the corrective advertising settlement by suggesting that the "UCLA" testing was valid and that he had settled only because our lawsuit was a nuisance. More important, however, Mr. Posey revived the Garwood test advertising with a new version which included additional testing done on Posey's new PORON® based pad. This new advertising began sometime late in 2004.

- 30. I became aware of the new Garwood ads in the late winter of 2005 after some correspondence with Mr. Posey. I was unaware until recently that in March 2005, Mr. Posey had ordered further testing of Posey's hip protector products in an effort to prepare for filing a lawsuit against HipSaver.
- 31. In any case, once we reviewed the new Garwood ads, we instructed our lawyer to demand an immediate retraction. This lawsuit followed.
- 32. While Posey finally withdrew the new Garwood advertising in the late summer of 2005, four years of false advertising by a company with the means to repeat its false claims again and again to customers has left HipSaver with little opportunity beyond the Veterans Administration. Our rate of growth is less than half Posey's. We are losing market share. Our revenue for 2006 was flat. We have no ability to access the private health care distribution and facility chains. The corrective advertising of 2004 might have reversed the trend against us, but it was undercut by Mr. Posey's marketing statement and the new Garwood ads. Posey's regret is meaningless. We remain frozen out, and we even face skeptical buyers who will no longer purchase from Posey because its product proved defective but will no longer consider us either.

- Since I began my work with soft hip protection garments, I have routinely 33. conducted laundry and drying tests of numerous materials. I have tested all of the pads used by HipSaver and all of the pads used by Posey. And as noted above, I have participated in a large scale test by the Veterans Administration. Based on my experience with institutional laundries operated by the VA and a number of private health care facilities and based on temperature readings I have taken at commercial laundries, the average wash temperature is 180°F and is frequently higher. I understand that the American Institute of Architects industry standard for health care facility construction calls for laundry temperatures at 160°F. The CDC high temperature wash guideline is for a minimum temperature of 160°F. HipSaver hip protectors are labeled to be washed at 200°F while Posey labeled its product at a minimum temperature of 160°F until 2005. And while I am aware of a low temperature CDC guideline, this guideline cannot be competently recommended for institutional settings because it requires use of bleach to offset the lower temperature. The hip protectors which are the subject of this lawsuit contain Lycra/Spandex stretch fibers and a urethane pad pouch covering. Bleach manufacturers recommend against bleach use on these components since routine use of bleach rapidly degrades the molecular structure of the base polymers.
- As noted above in paragraph 6, HipSaver has participated in two clinical studies. 34. The purpose of the study conducted by Jeffry B. Burl, MD, a physician at the Fallon Clinic, was to determine the extent to which a high compliance rate can be achieved among an elder group at high risk of hip injury. The compliance rate for patients who completed the study exceeded 93%. Moreover, it is significant as a matter of fact that not a single high risk patient was injured while wearing a HipSaver hip protector - even

though patients experienced 126 falls during the course of the study. While the Fallon study did not evaluate the statistical significance of zero injury, this was demonstrated and confirmed in a related study by George Gross and his colleagues in the Elder Service Plan study. Gross' study of frail elders over the course of 26 months determined that a zero hip injury rate among HipSaver wearers was statistically significant.

- 35. The HipSaver pad used in the Gross Study was substantially a design equivalent of the current HipSaver pad. Both pads use the same basic technology of an encapsulated visco-elastic damping urethane pad which I invented. In 2002, two years after the study ended, the physical therapists who ran the Gross Study informed us that they now used HipSavers that use the current HipSaver pad and that they had an additional 200 falls on the current HipSavers with no fractures.
- 36. HipSavers were also tested at Tampere University in 2000. The pads in the hip protectors tested at Tampere use the same foam as the current HipSaver pad. The foam material is the determinant of the force absorption of a hip protector pad. To add an extra margin of safety, current hip protector pads are even thicker than the pads tested at Tempere.

Edward L. Goodwin

Dated: 1/8/07

02820/00502 596287.1

EXHIBIT 3

CONFIDENTIAL, FILED UNDER SEAL

Exhibit 4

Lee Rash

From: Jeffrey Yates

Sent: Friday, July 27, 2001 5:30 PM

To: 'Robert.Weaver2@med.va.gov'; Gary Platzman

Cc: Dorene.Opava-Rutter@med.va.gov; Vicky Walters; Ernie Posey; 'jim.mcfall@med.va.gov'

Subject: Impact Data regarding Posey Hipsters



HipsterIII VA.doc

Greetings,

Thank you for your message Bob.

Attached to this email is an outline of the impact tests that were recently completed on the New Posey Hipster III product. The New Posey Hipster III absorbs 90% of the impact force of a fall (27% better performance than the current Hipster product).

Manufacturing will begin in a few weeks and I expect we will be in-stock and ready to ship near the end of August.

Vicky and I would like to meet with you early next week to review this study, present the falls research papers we have collected and most importantly, discuss the correlation of the data from the 1994 and 1999 Finnish and studies to the laboratory tests completed on our product this week through an independent testing facility.

If you are in agreement with the test results, Vicky and I would like to work with you on test protocols for a clinical trial on this product and any other products of interest. As Gary and I mentioned during our visit, Posey will provide a reasonable quantity of the Hipster III for clinical trials at NO COST. This is how confident we are that the new Posey Hipster III is the best energy absorbing external hip protector on the market.

I left voicemails for Dr. Rutter and Bob Weaver today (7/27) and will follow-up with another call on Monday to confirm receipt of this email.

I hope you have/had a great weekend.

Jeffrey Yates
Director of Marketing
J.T. Posey Company
5635 Peck Road
Arcadia, CA 91006
(626) 443-3143 x102
(626) 443-5064 - Fax
jyates@posey.com

----Original Message----

From: Robert.Weaver2@med.va.gov [mailto:Robert.Weaver2@med.va.gov]

Sent: Thursday, July 26, 2001 8:05 AM

To: Gary Platzman; Jeffrey Yates

Cc: Dorene.Opava-Rutter@med.va.gov

Subject: VA Hip protectors

Good morning,

I wanted to keep you both updated on our progress here at the falls clinic

in WLA. The executive manager of prosthetics, James McFall, cleared the

PC 0853

ahead to order 50 of the safehip model hip protectors. That decision is based on the current research that has been done on the device and our clearance to place an order ASAP. Dr. Opava-Rutter will review the literature of the hipsters when it arrives (did you send the info?). The falls prevention team is struggling with the product trial/clinical

on the hipsters b/c of the added commitment on our end getting clearance with research review board. Will keep you posted.

Thanks,

Bob Weaver, MS, RKT Site Coordinator



Company

5635 Peck Road Arcadia, CA 91006-0020 USA Web: www.posey.com

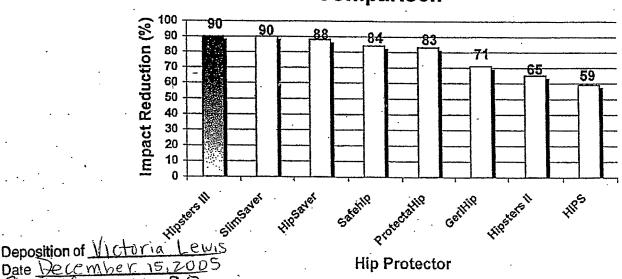
Victoria Walters Product Manager Tel: (626) 443-3143 Ext. 181 Fax: (626) 443-5064 Email: vwalters@posey.com

Posey Impact Test Results July 26, 2001

The graph below depicts the level of impact reduction from different commercially available hip protector products sold in the US when tested according to the following protocol.

- 1. Tests were conducted using a guided drop tower
 - missile weight = 72.5lbs
 - contact surface = 6 inches in diameter
 - drop height 28.5 inches
- Three drops per specimen
- 2. Three-minute recovery time between drops
- 3. All measurements were recorded in G-Force
- 4. A baseline of 2,660G was used to measure impact absorption. We estimate that 2,660G's is the approximate impact force to the area of the greater trochanter for a 120lb person falling from a height of 36".

Hip Protector Impact Reduction Rate Comparison



vaintiff's Exhibit

For Indentification

Denise Herft, CSR 1298?

Manufacturers and worldwide distributors of quality healthcare products since 1937

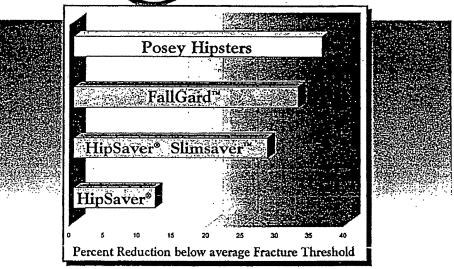
Exhibit 5





POSEY HIPSTERS PROVEN MOST EFFECTIVE IN WITRO TESTING

n in-vitro laboratory testing performed at UCLA, Posey Hipsters were shown effective in reducing the orce of impact in simulated falls to 36% below the average fracture threshold of the proximal femur, and 'osey Hipsters outperformed all other energy-absorbing foam hip protectors tested.



Data on file at J.T. Posey Company



Low Profile - All styles fit discreetly under men's and women's clothing.

POSEY HIPSTERS

Indications: Patients at risk for falling or hip fracture.

Protect your patients and residents against fall-related injuries with Posey Hipsters. Hipsters hip protectors feature impactabsorbing pads over the critical fracture area to minimize potential damage, including hip fractures, that can occur from a fall. The low-profile pads withstand institutional laundering and allow Hipsters to be worn discreedly under normal clothing.

CAT.#	STYLE	SIZE	WAIST SIZE	HIP SIZE
6016	Standard Brief	5	28-30	35-37
6017	Incontinent Brief	M	32-34*	39-41*
6018	Male Fly Brief	i.	36-38*	43-45
6019	EZ-On	XL	40-42*	47-49
6008	Replacement Pad	XXI	44-46*	51-53*



HS 000004

"FallGard"" is a trademark of FallGard", LLC. "HipSaver" and "SlimSaver" are trademarks of Hipsaver.

• TallGard" is a trademark of FallGard, LLC. "HipSaver" and "SlimSaver" are trademarks of Hipsaver.

• TallGard to the trademark of FallGard to the trademarks of Hipsaver.

• TallGard to the trademark of FallGard to the trademarks of Hipsaver.

• TallGard to the trademark of FallGard to the trademark of Hipsaver.

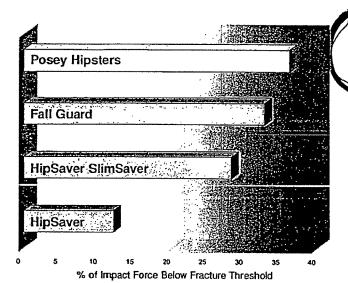
Posey News...

for Arkansas, N. Louisiana, Oklahoma, N. Texas: Winter 2004

The new year is upon us, and with it comes exciting news from Posey about new products, pricing, and in-service materials. Read on for more information about how Posey can help you provide quality health care to your patients and residents.

Injury Prevention:

Posey Hipsters Proven Most Effective in In-Vitro Testing



In in-vitro laboratory testing performed at UCLA, Poley Hipsters were shown effective in ducing the force of impact in simulate falls to 36% below the average fractive threshold of the proximal femur, and Posey Hipsters outperformed all other hip protectors tested.

Call me for a white paper with complete results of Hipsters laboratory testing.

EZ ON Hipsters #6019: Posey introduces the newest member of the Hipster family of products with the EZ ON Model. EZ ON Hipsters feature:

- Unisex design for use with virtually any under garment or incontinence wear.
- Fast and easy patient care. Great fit and comfort in sizes Small to XXL.
- Washable leave pads in for convenience or remove them for extended life!
- Replaceable pads. #6008
- A 24-hour wear product with the Posey pad that molds to the body shape for comfort & compliance!
- EZ On Hipsters are ideal for the shower!



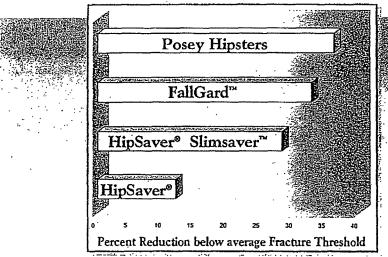
HS 000007

POSEY

1-800-44-POSEY www.posey.com

POSEY HIPSTERS PROVEN MOST EFFECTIVE IN IN-VITRO TESTING

In in-vitro laboratory testing performed at UCLA, Posey Hipsters were shown effective in reducing the force of impact in simulated falls to 36% below the average fracture threshold of the proximal femur, and Posey Hipsters outperformed all other energy-absorbing foam hip protectors tested.



Data on file at J.T. Posey Company



Low Profile - All styles fit discreetly under men's and women's clothing.

POSEY HIPSTERS

Indications: Patients at risk for falling or hip fracture.

Protect your patients and residents against fall-related injuries with Posey Hipsters. Hipsters hip protectors feature impactaborbing pads over the critical fracture area to minimize potential damage, including hip fractures, that can occur from a fall. The low-profile pads withstand institutional laundering and allow Hipsters to be worn discreetly under normal clothing.

CAT. #	STYLE	SIZE	WAIST SIZE	HIP SIZ
5016	Standard Brief	\$	28-30"	35-37*
6017	Incontinent Brief	M	32-34	39-41*
5018	Male Fly Brief	L	36-38"	43-45
6019	EZ-On	XL.	40-42	47-49*
6008	Replacement Pad	XXL	44-46	51-53
	Her use with model 400101			

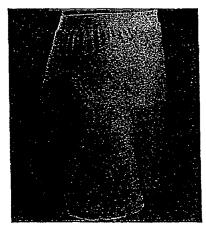


HS 000108

[&]quot;FallGard"" is a trademark of FallGard", LLC. "HipSaver" and "SlimSaver" are trademarks of Hipsaver."

Exhibit 6

POSEY HIPSTERS HELP PROTECT AGAINST INJURY FROM FALLS



It's a long way down for residents at risk of injury from falls. You can greatly reduce that risk with Posey Hipsters. The Hipsters' high energy-absorbing foam pads are positioned precisely over the hip bones, increasing the odds of surviving a fall uninjured. The Hipsters are comfortable and slim enough to be virtually undetectable under clothing. By offering increased protection, Hipsters relieve residents' anxiety about falling and enhance their quality of life.

- High impact-absorbing viscoelastic pads protect hip bones against injury from falls
- Soft, comfortable pads improve compliance versus hard-shelled products
- Washable to CDC standards for soiled linen without removing the pads
- 100% latex-free
- Five sizes for correct fit
- Discreet, low-profile pads are virtually undetectable under clothing

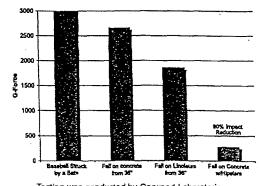


Low Profile -All styles fit discreetly under men's and women's clothing.



Posey Hipsters Proven Effective in Laboratory Test

An independent laboratory study was conducted to determine the most effective impact absorbing material. A test was created that would simulate a fall causing direct impact to the greater trochanter. In this study, a weight was released in a guided drop to simulate a 120 lb. subject falling from a height of 36°, or the estimated height of the hip above the floor for a typical nursing home resident. The baseline measurement of impact force was determined to be a fall directly onto concrete. The G-Force of a fall under this scenario was 2,660G's and, for purposes of comparison, is just slightly less impact force than that of a baseball being struck by a bat. In this extreme test, the low profile Posey Hipster reduced the impact force on average by 90% and showed excellent impact energy absorption.



Testing was conducted by Garwood Laboratories.

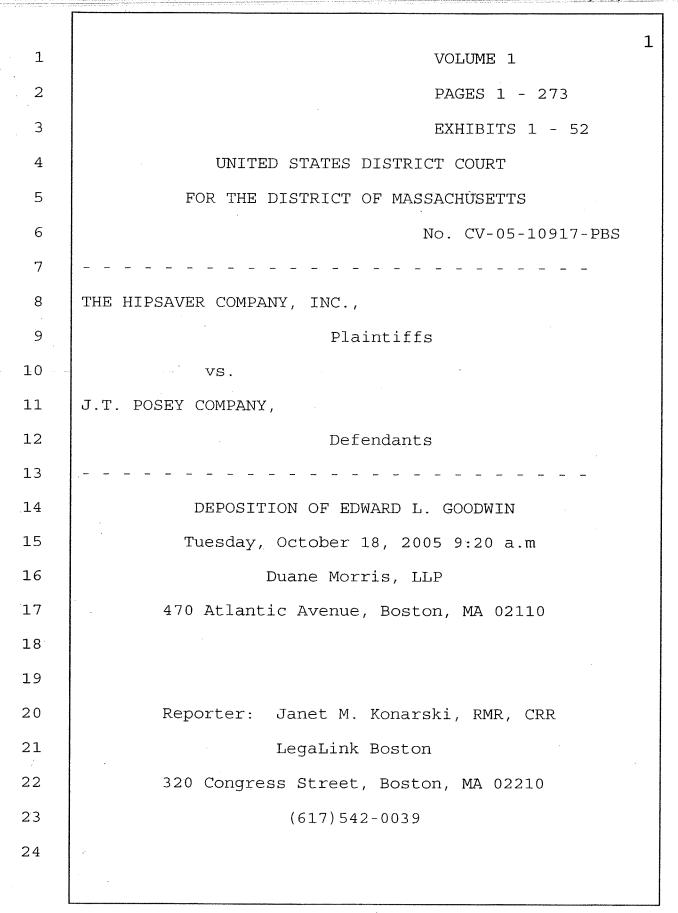
Data on file at J.T. Posey Company *Source: www.madsci.org

Special offer: 30-day no-risk free trial.

Test the Posey Hipsters for yourself with no obligation to buy.

PC 1744

Exhibit 7



	2
1	APPEARANCES:
2	
3	SHELDON & MAK
4	(By Douglas H. Morseburg, Esquire)
5	225 South Lake Avenue
6	Pasadena, California 91101
7	(626)796-4000
8	Counsel for the Defendant
9	
10	BROMBERG & SUNSTEIN LLP
11	(By Edward J. Dailey, Esquire, and
12	Courtney M. Quish, Esquire)
13	125 Summer Street
14	Boston, Massachusetts 02110
15	(617)443-9292
16	Counsel for the Plaintiff
17	
18	
19	
20	
21	
22	
23	
24	

	22
1	A. Yes.
2	Q. How many employees does HipSaver have?
3	A. Seven.
4	Q. Does it have any people who work for it on
5	a contracting basis?
6	A. Yes.
7	Q. How many?
8	A. Two.
9	Q. Is it fair to say that HipSaver makes
10	solely soft hip protectors?
11	A. Yes.
12	Q. Some products are called HipSaver and some
13	are called SlimSaver, right?
14	A. No.
15	Q. Does HipSaver sell a product with the word
16	slim in it?
17	A. Yes.
18	Q. Is it SlimFit?
19	A. Yes.
20	Q. What is the difference between a product
21	marketed under the name HipSaver and one marketed under
22	the name SlimFit?
23	A. They're all under the umbrella of
24	HipSaver. SlimFit is generally meant to be for the

A. No.

23

24

Q. I notice in the materials that you

What Garwood test are you talking about?

24

Q.

24

Q. Did you think that Posey was being released from any claim that arose prior to the date of the settlement agreement?

MR. DAILEY: Objection.

- A. I don't have an answer for you.
- Q. Did you not give the terms of the release any thought at all?

MR. DAILEY: Objection.

- A. I've already explained to you what my interpretation of the settlement was, and if you want to say that I don't have a legal mind, that's fine. I do have a mind for ethical commerce, and your client engaged in a false, deceptive, disparaging advertising campaign, and in order to save my company I had to have that removed, and this settlement achieved that. And I had hoped that it would pave the way for a future where Posey would understand that you can't go and get a junk test and manipulate the data and try to bury a small competitor with it.
- Q. Did you have any discussions with anybody prior to the time you signed the settlement agreement about the extent of the claims that would be released by signing the settlement agreement?
 - A. My primary interest was in having the

50 1 UCLA, fraudulent UCLA test removed, and this settlement 2 agreement did that. 3 Ο. But, my question was: Did you have any discussions with anybody --4 5 Α. No. 6 Q. -- about the -- did you pay any attention 7 to Paragraph 11 when you read the settlement agreement --8 9 MR. DAILEY: Objection. 10 -- before you signed it? 11 Α. I don't know how many times I can try to 12 answer the same question, that I am not a lawyer, nor 13 would I want to be one, and -- not to insult Mr. Dailey 14 here, but I go by the spirit, okay? And the spirit of 15 this settlement was that he was to remove and put out a corrective statement for his false and fraudulent UCLA 16 17 test, where he manipulated the data and made big bar 18 charts in his catalogs to try to bury HipSaver, false 19 comparative advertising, proven. And I wanted that 20 removed, so I could go back to work making HipSavers, 21 rather than spending all my time in litigation against 22 Posey. 23 Ο. Does that mean you didn't pay any 24 attention to Paragraph 11 at the time you signed the

1	settlement agreement or before you signed the
2	settlement agreement?
3	MR. DAILEY: Objection.
4	A. I read the whole document.
5	Q. At the time you signed the settlement
6	agreement, did you intend to release Posey from any
7	claims that you could have brought against them up
8	until the date of the settlement agreement?
9	MR. DAILEY: Objection.
10	A. I don't have an answer.
11	Q. You don't know?
12	A. I don't have an answer.
13	Q. Does that mean you don't know whether you
14	intended to release them or not?
15	A. I think it would require further thought.
16	It doesn't mean that I don't know.
17	Q. Do you want to think about it for a few
18	minutes?
19	A. That won't be long enough.
20	Q. The lawsuit in Posey 1 let me just
21	withdraw that. Is it okay if we refer to the lawsuit
22	that occurred in 2004 as Posey 1?
23	A. Yes.
24	Q. The complaint that you brought against

	52
1	Posey in Posey 1 concerned basically what we've called
2	the UCLA White Paper, right?
3	A. And subsequent advertising that flowed
4	from it.
5	Q. When you signed the settlement agreement,
6	did you intend to release Posey from any claims that
7	were the subject of any advertising mentioning the
8	White Paper up until the time of the settlement
9	agreement?
10	MR. DAILEY: Objection.
11	A. The UCLA White Paper?
12	Q. Yes.
13	A. I'm sorry. Could you ask the question
14	again.
15	MR. MORSEBURG: Could you read the
16	question back, please.
17	(The pending question was read by the
18	reporter as requested.)
19	A. Yes. I believe that's true.
20	Q. Were there any other claims that you
21	thought were included in the release?
22	MR. DAILEY: Objection.
23	A. No.
24	Q. So, is it fair to say your understanding

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of the settlement agreement is that it only included claims against Posey that HipSaver could have asserted that arose out of the advertising related to the UCLA White Paper up until the time the settlement agreement was executed?

> MR. DAILEY: Objection.

- That was the effective result sought, and Α. that was achieved.
- Your intention in signing the settlement ο. agreement was only to release those claims. Objection. MR. DAILEY:
- It was, as I said before, it was to release those fraudulent test claims, that fraudulent advertising, that misleading, deceptive advertising that he put in his catalogs, to have all of that removed and have the White Paper removed and to put out a corrective announcement admitting that he had whatever it was, manipulated the data and had a student do a test that then he turned around and represented that UCLA did. All of the things that he did to set up a fraudulent test against HipSaver, to advertise against HipSaver were part of the release.
- But, as far as you were concerned, you 0. only intended to release claims that related to the

Case 1:05-cv-10917-PBS

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UCLA White Paper or relatd to advertising related to the UCLA White Paper?

- Α. That was the sought-after result.
- Q. What did you understand Posey was releasing HipSaver from?

MR. DAILEY: Objection.

- He had a counterclaim against me, and he Α. dropped that with prejudice, which has now been resurrected, the exact same counterclaim as in Posey 1, exact same claim. And that's what he released me from.
- Did you intend to secure from Posey -- and 0. I want to limit to when you signed this settlement agreement. Is that clear? At the time you signed this settlement agreement, did you intend to secure from Posey a release of any claim of any nature up until the time of the settlement agreement?

MR. DAILEY: Objection.

It wasn't my concern, because he has no Α. claims. He never had a valid claim against HipSaver. Although he took out a countersuit in Posey 1, the claim was totally baseless, and it was removed with prejudice. He has no claim against HipSaver. He never He's the one that copied HipSaver and then went out and false advertised it and tried to put me out of

<u>[</u>.

	60
1	commercial advertising use of the results or analysis
2	related to such testing without giving the other party
3	at least thirty (30) days advanced written notice of
4	the results or analysis." Did I read that paragraph
5	correctly?
6	A. Yes.
7	Q. One of the claims that HipSaver is
8	bringing in this lawsuit is that Posey advertised a
9	study by Garwood in its advertising, right?
10	A. That's correct.
11	Q. And you contend that Posey was supposed to
12	give you 30 days' notice prior to bringing out this
13	advertisement that made reference to that advertising.
14	Have I stated your position correctly?
15	A. Yes.
16	Q. And they didn't do that, right?
17	A. No, they didn't.
18	Q. What damage did HipSaver suffer as a
19	consequence of the failure to get that notice?
20	MR. DAILEY: Objection.
21	A. The advertisement was placed live, and we
22	didn't have an opportunity to know exactly when these
23	ads were placed, and as I subsequently found out, there
24	is a backup data on file from J.T. Posey Company that

1	lists the products of HipSaver, as well as several
2	other people in the market, essentially implying they
3	were a list of also rans, meaning that Posey puts his
4	results, which declare 90 percent reduction in impact
5	force, in with a packet that he sends to people, but he
6	doesn't put the results of the other hip protectors.
7	When presented to a medical director,
8	who might inquire to receive this package, they could
9	possibly make the determination to use Posey Hipsters
10	in a facility of nursing homes encompassing 200, 300
11	homes. So, if the test is found to be false, there is
12	a lot of damage done by the advertising and the
13	mechanism by which he employed the advertising.
14	MR. MORSEBURG: Move to strike on the
15	grounds it's not responsive.
16	Q. My question was a little bit different. I
17	understand that you contend you were damaged by the
L8	advertising.
L9	A. Right.
20	Q. But, how are you damaged by the failure to
21	get advanced notice of the advertising?
22	MR. DAILEY: Objection.
23	A. I'm sorry. I just don't understand what
24	you're asking.

1	involved in, besides Posey 1?
2	A. That's it.
3	Q. How about you, personally, how many
4	lawsuits have you been involved in?
5	MR. DAILEY: Objection. Asked and
6	answered.
7	Q. I know you've been involved in one with
8	the City of Boston. Any others besides that?
9	A. No.
10	Q. Generally, what was that lawsuit about?
11	A. It was a police misconduct case.
12	Q. What year was that?
13	A. 1987.
14	Q. Earlier we were talking about Posey's
15	advertising in 2002 that made reference to the Garwood
16	study. Why didn't you object to it when you saw it the
17	first time?
18	MR. DAILEY: Objection.
19	A. As I said before, there were a few things
20	going on. First of all, I was having to go to all the
21	VA hospitals to do inservices, and I was having to
22	counter the fact that Posey copied my product and was
23	flooding the marketplace with free samples, and just
24	basically trying to keep my head above water at the

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And, as I said, I dismissed the ad as junk science for a variety of reasons, and mistakenly interpreted that the average health care pracitioner would be smart enough to realize that it was junk science, but now that I've been in the field longer, I know that is not the case. That it tested Posey as advertised like that indeed can be a door opener for a product that requires some sort of validation.

- Q. What does the term "knockoff" mean to you?
- "Knockoff" means that stealing the Α. property or stealing the idea, the product idea of an original inventor and then offering the product for sale in the marketplace.
- 0. Why didn't you sue Posey when they copied your product?

MR. DAILEY: Objection.

- When Posey copied my product in 2002, I Α. had no basis for a lawsuit, because my patent had not issued. And, contrary to the assertions of the Posev Company, I have never accused him of infringing on any patent.
- Q. You've accused Posey of knocking off other peoples' products, right?
 - Α. Yes.

1	Q. Are you aware of any out-of-pocket losses
2	that HipSaver has suffered as a consequence of the acts
3	complained of in the complaint?
4	A. When you say "out-of-pocket," I don't
5	understand what you mean by that.
6	Q. Anything that you can think of that you've
7	had to spend that you wouldn't have had to spend, but
8	for the fact that Posey did something bad?
9	A. The cost of this lawsuit.
10	Q. Anything else?
11	A. Lost market share, lost opportunity,
12	wasted time.
13	Q. If your market share is the same today as
14	it was a year ago, how could you have lost market
15	share?
16	MR. DAILEY: Objection.
1 7	A. Well, it's a growing market, although
18	slowly, so I can lose growth potential. When I said
19	"about the same," please insert the caveat I said I'd
20	have to provide these numbers through my attorney,
21	because I wasn't sure exactly what. It's not something
22	I have on the top of my head.
23	Q. When you say "the numbers," are you
24	talking about gross sales numbers?

1	A. Yes.
2	MR. MORSEBURG: Let's talk about those.
3	Let's have this marked as exhibit next in order, which
4	I think is 13.
5	(Document Bates stamped HS2
6	000034 marked Exhibit 13.)
7	BY MR. MORSEBURG:
8	Q. Have you had a chance to look at the
9	document which has been marked as Exhibit 13?
10	A. Yes.
11	Q. Have you ever seen it before?
12	A. Yes.
13	Q. What is it?
14	A. That is the approximate units per year for
15	HipSaver sales.
16	Q. Where did you get these let me ask:
17	Did you have anything to do with this piece of paper
18	A. Yes.
19	Q being put together?
20	A. Yes.
21	Q. Did you, what, look on your computer or
22	consult your financial statements or something to get
23	numbers to put on this piece of paper?
24	A. Financial statements.

1 -	143 Q. In arriving at the numbers on the piece of
	_
2	paper for the approximate units sold per year, did you
3	take your gross income and divide it by an average
4	price or something like that?
5	A. Yes.
6	Q. Is that how you did it?
7	A. Yes.
8	Q. So, we're talking approximately your sales
9	in 2001 were about 13,000 units. Is that true?
10	A. Right.
11	Q. And in 2002, your approximate number of
12	units sold is 18,564?
13	A. Yes.
14	Q. And in 2003, your approximate number of
15	units sold was 30,213?
16	A. Yes.
17	Q. And in 2004, your approximate number of
18	units sold was 44,382?
19	A. Yes.
20	Q. And do you have any idea as to
21	year-to-date 2005, whether your sales are running
22	higher than or lower than last year or about the same?
23	A. They're higher, but I'm not sure how much.
24	Q. Do you think they're higher by if you

	4.4
1	look at the numbers here, your sales from 2001
2	A. I'm sorry. Are you talking about I
3	thought you were talking about 2004. Okay. All right.
4	I got confused. Yes. They're higher, but I'm not sure
5	how much.
6	Q. I was going to ask sort of a related
7	question, but I'm going to work up to it.
8	A. Sure.
9	Q. And in your year-to-year sales from 2001
10	to 2002 I mean in 2002, your sales increased
11	somewhere in the neighborhood of, what, 40 percent over
12	2001? Is that approximately right?
13	A. Yes.
14	Q. And then in 2003, your sales increased
15	approximately, what, 60 percent over 2002? Does that
16	look about right?
17	A. Yes.
18	Q. And then in 2004, your sales increased
19	approximately 50 percent over 2003? Does that look
20	about right?
21	A. Yes.
22	Q. Do you have any sense that your sales have
23	increased 50 percent in 2005 more than 2004?
24	MR. DAILEY: Objection.
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	145
1	A. No. It's not 50 percent.
2	Q. Is it higher or lower than 50 percent?
3	A. It's much lower.
4	Q. Much lower than 50 percent. Do you have
5	any sense but, you said your sales numbers in 2005
6	have increased over 2004 year to date. Is that what
7	you testified to?
8	A. That's correct. Yes.
9	Q. And do you have a sense of what percentage
10	your sales have increased over 2004 year to date?
11	A. No, I don't.
12	Q. If you wanted to figure that out, how
1 3	would you figure it out?
14	A. I would take the total revenue and divide
15	it by 28, which is the average unit sale plus shipping
16	and handling inclusive of shipping and handling,
17	rather.
18	Q. The average price of HipSaver product is
19	the same, less than or more than last year?
20	A. It's been the same for the last five
21	years.
22	Q. Generally speaking, are Posey's products
23	cheaper for the institution than they are for buying a
24	HipSaver product?

Q. Your income, your sales? I'm trying to figure out what your profit is. You say you have no reported profit?

A. Right. There is one other big category in there. I do a SEP IRA for everybody in the company, and it's a hundred percent contributed, 25 percent of their salary, so that's -- what is happening here is you're asking me to mentally go through all my things, which I don't have the advantage of looking at an itemized list, so that is why I'm thinking of these things after you asked me.

- Q. Do you have any idea of the amount of money by which HipSaver has been damaged by any of the acts complained of in the complaint?
- A. The whole hip protector market has been damaged by Posey. HipSaver, in particular, because he copied the entire HipSaver, but his false advertising and false use of the UCLA test, this Garwood test that I can't wait to see the results of, is all just false, unfair competition, and he's advertising this High Durability to compete against HipSaver now, and that is not true.

Posey has depressed the marketplace for hip protectors. His pad is not even on top of the

149 1 trochanter. It doesn't cover the trochanter. So, when 2 people have a hip fracture in a Posey product, they 3 say, well, why bother with all the work and expense of 4 buying hip protectors, and they just chuck it, and that 5 is the end of it. They fall apart in the laundry. 6 So, if the hip protector market -- we 7 have 70,000 hip fractures in the United States in 8 nursing homes every year. That is roughly ten a 9 So, for the time we've been here today, there 10 has been 60 hip fractures in nursing homes, 70. The 11 potential market for this intervention is huge. It's 12 like in the nursing homes it's probably a \$25 million 13 category, and I do about 1. -- say a 14 million-and-a-half, for the sake of argument. 15 Posey does 2 million. I don't know what he does. So, 16 the bottom line is that your client has damaged the 17 field of hip protection, but more so than that, he's 18 put a dangerous and defective product on the market, 19 which has given a negative impression to care givers 20 all around the country. His product falls apart in the 21 That is proven. His product doesn't cover 22 the trochanter, that is proven, and his product is 23 falsely advertised in every test. Everything on this 24 page is false advertising (indicating). This warning

	151
1	A. I believe we're going to hire, retain an
2	expert, economist to work those numbers out.
3	Q. As you sit here today, is it fair to say
4	you don't have any idea what the number would be?
5	MR. DAILEY: Objection.
6	A. There is a number, but that is to be
7	determined.
8	Q. Right. There is a number. You just don't
9	know what it is. Is that fair to say?
10	A. That's right.
11	Q. Has your advertising expense increased
12	this year over last?
13	A. No.
14	MR. DAILEY: Objection. Asked and
15	answered.
16	Q. Has HipSaver's reputation been harmed by
17	any of the acts which are the basis of the complaint?
18	MR. DAILEY: Objection. Asked and
19	answered.
20	A. Before Posey introduced his knockoff of
21	HipSaver, we would send a sample to a nursing home, and
22	generally they would show it around and start
23	purchasing. Not always, but a lot of times. After
24	Posey put his defective product on the market, we might

7	7	153
1	Α.	105.
2		MR. MORSEBURG: Let's have this marked as
3	exhibit next	in order a document called Complaint.
4		(Complaint marked Exhibit 14.)
5	BY MR. MORSE	BURG:
6	Q.	Have you had a chance to look at the
7	document whi	ch has been marked as Exhibit 14?
8	Α.	Yes.
9	Q.	Have you ever seen it before?
10	Α.	Yes.
11	Q.	It purports to be the complaint that was
12	filed in thi	s case. Prior to the time it was filed,
13	did you revi	ew it?
14	Α.	Yes.
15	Q.	Did you authorize it being filed?
16	Α.	Yes.
17	Q.	Do you understand that the basis of the
18	complaint is	a false advertising campaign begun in
19	2005?	
20		MR. DAILEY: Objection.
21	Q.	Is that what you understand?
22	Α.	I understand that is a portion of the
23	complaint, ye	es.
24	Q.	And another portion of the complaint is it

Objection.

MR. DAILEY:

24

between the time of the settlement and the date of this e-mail, other than the e-mail that we saw, or the letter we saw in which he asked you to provide the laundry validation data?

A. From the time of the settlement until this incident here, he sent me a letter telling me that he had removed the corrective statement from his web site. And this is about in November, I believe. And I sent him an e-mail -- there was one exchange of e-mails between the two of us about his corrective statement in the catalogs, and I didn't believe that he did it, because I really don't believe that he does anything he says. And he said he put it on a jacket wrapper of the catalog, so it was not in the catalog. So, once again, we have a what should be an important document on a jacket wrapper that people are going to rip off and throw away. Typical Posey.

Q. Does the reference in the last sentence to "Leave me alone" have anything to do with him putting the notice on the jacket wrapper?

A. No. It has to do with him -- it became clear to me right after the settlement that he was coming after HipSaver again with new tests, with this resurrected Garwood test, with this high durability pad

Q.

Ernie Posey on April 2, 2005?

	and going around and telling customers where Hipsters
	had previously fallen apart that he has a new high
	durability Hipster and going after my customers and
	telling them the same thing. And then when I got this
	letter about the laundry, it was just I had hoped that
	Ernie Posey and I were done, but when I got this letter
	about the laundry, I said this is never going to end,
	because he's now going to find a way to keep moving
	forward with what he says is a high durability Hipster,
	which really isn't.
	Q. Did you view the putting of the notice on
- 1	
	the wrapper of the catalog as a violation of a
	the wrapper of the catalog as a violation of a settlement agreement somehow?
The second secon	
	settlement agreement somehow?
	settlement agreement somehow? A. No.
	settlement agreement somehow? A. No. MR. MORSEBURG: Let's have marked as
	settlement agreement somehow? A. No. MR. MORSEBURG: Let's have marked as exhibit next in order a one-page document purporting to
	settlement agreement somehow? A. No. MR. MORSEBURG: Let's have marked as exhibit next in order a one-page document purporting to be an e-mail from HipSaver to Ernie Posey.
	A. No. MR. MORSEBURG: Let's have marked as exhibit next in order a one-page document purporting to be an e-mail from HipSaver to Ernie Posey. (E-mail dated 4/2/05
	A. No. MR. MORSEBURG: Let's have marked as exhibit next in order a one-page document purporting to be an e-mail from HipSaver to Ernie Posey. (E-mail dated 4/2/05 marked Exhibit 42.)

Is it a true copy of an e-mail you sent to

1	ERRATA SHEET
2	I, EDWARD L. GOODWIN, do hereby certify that I
3	have read the foregoing transcript of my testimony, and
4	further certify that it is a true and accurate record
5	of my testimony (with the exception of the corrections
6	listed below).
7 ·	PAGE LINE CORRECTION
8	21 17 JWO
9	19 & Helen Brogner.
10	
11	22 W
12	162 13 Wylhard Barre
13	
14	
15	
16	
17	
18.	
19	_DN
20	Signed under the pains and penalties this
21	day of Noluber, 2005.
22	61,01
23	- ally filler
24	EDWARD L. GOODWIN
1	

	272
1	CERTIFICATE
2	COMMONWEALTH OF MASSACHUSETTS
3	SUFFOLK, SS.
4	I, Janet M. Konarski, a Registered Merit
5	Reporter and a Notary Public within and for the
6	Commonwealth of Massachusetts do hereby certify:
7	THAT EDWARD L. GOODWIN, the witness whose
8	testimony is hereinbefore set forth, was duly sworn by
9	me and that such testimony is a true and accurate
10	record of my stenotype notes taken in the foregoing
11	matter, to the best of my knowledge, skill and ability.
12	IN WITNESS WHEREOF, I have hereunto set my hand
13	this 30th day of October, 2005.
14	Janet M. Kouarski
15	GANET M. KONARSKI
16	Notary Public
17	
18	My Commission Expires: CERTIFIED TRANSCRIPT
19	July 19, 2007 LEGALINK BOSTON
20	
21	
22	
23	
24	

Edward L. Goodwin

11/30/2005

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		1
1	VOLUME 1	
2	PAGES 1 - 146	
3	EXHIBITS: 55 - 63	
4	UNITED STATES DISTRICT COURT	
5	FOR THE DISTRICT OF MASSACHUSETTS	
6	No. CV-05-10917-PBS	
7		
8	THE HIPSAVER COMPANY, INC.,	
9	Plaintiffs	
10	vs. CONFIDENTIAL	
11	J.T. POSEY COMPANY,	
12	Defendant	
13		
14	AND RELATED COUNTERCLAIM.	
1 5		
16	VIDEOTAPED DEPOSITION OF EDWARD L. GOODWIN	
17	Wednesday, November 30, 2005 12:30 p.m	
18	Duane Morris, LLP	
19	470 Atlantic Avenue, Boston, MA 02110	
20		
21	Reporter: Janet M. Konarski, RMR, CRR	
22	LegaLink Boston	
23	320 Congress Street, Boston, MA 02210	
24	(617)542-0039	
•		

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1	APPEARANCES:	2
2		
3	BROMBERG & SUNSTEIN LLP	
4	(By Edward J. Dailey, Esquire)	
5	125 Summer Street	
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14	(626) 796-4000	
15	Counsel for the Defendant	
16		
1,7	ALSO PRESENT:	
18	Ernest Posey, Jr.	
19	Jason LaChapelle, Videographer	
20		
21		
22		
23		
24		

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43:37 دـــ:	1	Q. The third version of the product?
15:43:38	2	A. Yes.
15:43:49	3	Q. Well, the current HipSaver product hasn't
15:43:52	4	been on the market since 1995, has it?
15:43:56	5	A. Well, I think what you have to take into
15:43:57	6	consideration here is that I developed the encapsulated
15:44: 01	7	pad in 1995, and that is the essence of the invention
15:44:06	8	that makes it the leader in hip protection, and Posey
15:44:11	9	copied that in 2002. So, those are the two products
15:44:15	10	that were being compared.
15:44: 22	11	Q. Well, the product that was introduced in
15:44:24	12	1995, could you machine wash and dry that at
144:26	13	250 degrees Fahrenheit?
15:44:29	14	MR. DAILEY: Objection.
15:44:30	15	A. No.
15:44:30	16	Q. So
15:44:31	17	MR. DAILEY: There is no such statement in
15:44:32	18	the document, Mr. Sheldon, and you know that.
15:44:34	19	Q. Well, there actually is, sir, if you look
15:44:37	20	at Line 6. Does that help you?
15:44:43	21	A. What it refers to is our current product.
15:44:48	22	Q. So, Line 6 is comparing the current
15:44:50	23	products, and Line 5 is comparing the 1995 product
15:44:56	24	against a later Posey product; is that correct?
e di		

. *	1	145
103:38	1	ERRATA SHEET
16:03:38	2	I, EDWARD L. GOODWIN, do hereby certify that I
16:03:38	3	have read the foregoing transcript of my testimony, and
16:03:38	4	further certify that it is a true and accurate record
16:03:38	5	of my testimony (with the exception of the corrections
16:03:38	6	listed below).
16:03:38	7	PAGE LINE CORRECTION
16:03:38	8	
16:03:38	9	
16:03:38	10	· · · · · · · · · · · · · · · · · · ·
16:03:38	11	
16:03:38	12	
103:38	13	
16:03:38	14	
16:03:38	15	<u>·</u>
16:03:38	16	
16:03:38	17	
16:03:38	18	
16:03:38	19	
16:03:38	20	Signed under the pains and penalties this
16:03:38	21	day of, 2005.
16:03:38	22	
16:03:38	23	
16:03:38	24	EDWARD L. GOODWIN

. •		146
1.:12:17	1	CERTIFICATE
15:12:17	2	COMMONWEALTH OF MASSACHUSETTS
15:12:17	3	SUFFOLK, SS.
15:12:17	4	I, Janet M. Konarski, a Registered Merit
15:12:17	5	Reporter and a Notary Public within and for the
15:12:17	6	Commonwealth of Massachusetts do hereby certify:
15:12:17	7	THAT EDWARD L. GOODWIN, the witness whose
15:12:17	8	testimony is hereinbefore set forth, was duly sworn by
15:12:17	9	me and that such testimony is a true and accurate
15:12:17	10	record of my stenotype notes taken in the foregoing
15:12:17	11	matter, to the best of my knowledge, skill and ability.
15:12:17	12	IN WITNESS WHEREOF, I have hereunto set my hand
10:12:17	13	this 4th day of December, 2005.
15:12:17	14	
15:12:17	15	Janet M. Kanarski
15:12:17	16	Wotary Public
15:12:17	17	
15:12:17	18	My Commission Expires: CERTIFIED TRANSCRIPT LEGALINK BOSTON
15:12:17	19	July 19, 2007
	20	
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1	VOL. III, PAGES 1- 136
2	UNITED STATES DISTRICT COURT
3	FOR THE DISTRICT OF MASSACHUSETTS
4	CASE NO. CV-05-10917 PBS
5	
6	THE HIPSAVER COMPANY
7	Plaintiff
8	V.
9	J.T. POSEY COMPANY
10	Defendant
11	AND RELATED COUNTERCLAIM
12	CONFIDENTIAL
13	Confidential - Attorneys' Eyes Only
14	·
15	Videotaped Deposition of Edward L. Goodwin
16	Friday, March 3, 2006
17	10:00 a.m.
18	Duane Morris
19	470 Atlantic Avenue
20	Boston, Massachusetts
21	
22 _	Reporter: Deborah Roth, RPR/CSR
23	
24	
Į.	

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2
 1
      PRESENT:
 2
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      Edward J. Dailey, Esq.
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      Boston, Massachusetts
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 9
      Douglas H. Morseburg, Esq.
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      626 796 4000
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14
      For the Defendant
15
16
17
18
     ALSO PRESENT:
                      Wesley Hicks, Videographer
19
20
21
22
23
24
```

		CONFIDENTIAL - ATTORNEYS' EYES ONLY
		45
1_:21:18	1	Q. How long has HipSaver said, "Wash at 200
11:21:22	2	degrees Fahrenheit"?
11:21:23	3	MR. DAILEY: Objection.
1 1:21:24	4	A. It's been a long time. I couldn't five
11:21:31	5	years, six years, seven years, maybe.
11:21:38	6	Q. You see the next line down, where it has a
11:21:48	7	triangle: "Bleach: low concentrations"?
11:21:52	8	A. Yes.
11:21:53	9	Q. How long has HipSaver had a laundry label
11:21:57	10	that says, "Bleach: low concentrations"?
11:22:00	11	A. I think it's about three or four years,
11:22:14	12	maybe.
122:21	13	Q. HipSaver formerly had a label that said
11:22:24	14	"Don't bleach," right?
11:22:25	15	A. That's right.
11:22:27	16	Q. Why did you make the change from "no
11:22:40	17	bleach" to "bleach: low concentrations"?
11:22:42	18	A. We were talking with people who were using
11:22:50	19	low concentrations of bleach, and also did some
11:22:55	20	experimentation on bleach and low concentrations.
11:23:00	21	It bleach is going to, in any
11:23:05	22	concentration, lead to a more rapid degradation of
1 1:23:09	23	any product. However, in low concentrations, it

the amount of degradation is not objectionable.

11:23:17 24

. . .

	_		50
30:28	1	Q. What company manufactured	
11:30:32	2	A. EAR Specialty Composites.	
11:30:36	3	Q. That's a company that has been referred to	
11:30:40	4	in the litigation as EAR?	
11:30:42	5	A. Yes.	
11:30:42	6	Q. And Confor foam is an open-cell foam; is	
11:30:59	7	that right?	
11:30:59	8	A. Yes.	
11:30:59	9	Q. And the LS foam is what type of foam?	
11:31:04	10	A. I believe it's closed-cell.	
11:31:13	11	Q. Your Website makes reference to some	
11:31:16	12	testing that was performed on HipSaver products,	
131:19	13	right?	
11:31:20	14	A. That's correct.	
11:31:22	15	Q. Is one of the tests that is referred to on	
11:31:24	16	the Website the test which is the subject of	
11:31:28	17	Exhibit 129?	
11:31:30	18	A. This test is referenced, but the data is	
11:31:35	19	presented from the University of Tampere.	
11:31:39	20	Q. This is one of tests that you refer to when	
11:31:43	21	you make claims that your product was tested at	
11:31:46	22	prestigious universities, Harvard and Tampere?	
11:31:46	23	A. That's right.	
11:31:52	24	Q. That is the only one you talk about?	

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51 1..31:55 1 Α. Absolutely. 11:31:56 The products that you use in your pads 2 11:32:02 these days is made by Lendell Corporation, right? 3 11:32:06 Α. That's correct. 4 11:32:07 And it's foam EP -- it's their EP foam? 5 0. 11:32:14 6 Α. Yes, it is. 11:32:15 7 And they have a couple of different models: ο. 11:32:20 1, 2, 3 and 4, which designate different colors of 8 11:32:23 9 the foam; does that sound right to you? 11:32:25 · A. That's right. 10 Is that foam the same foam that is the 11:32:25 11 Q. 11:32:28 subject of this test which is the subject of 12 1..32:30 Exhibit 129? 13 11:32:31 14 It's a substantial equivalent. Α. 11:32:38 And how is it substantially equivalent? 15 ٥. 11:32:41 Because they test biomechanically -- the 16 Α. foam we are using now is biomechanically a little 11:32:46 17 11:32:50 bit better than the Harvard test. 18 So by "substantially equivalent," do you 11:32:51 19 Q. 11:32:54 mean that the results of the test are substantially 20 equivalent, or do you mean that the foam is 11:32:56 21 substantially equivalent? 11:32:58 22 Both. **11:**32:59 23 Α. The foam, which is the subject of this test 11:33:02 24 Q.

/ 133:08	1	which is mentioned in 129, was an open-cell foam	52
11:33:17	2	with two layers of foam on either side of it,	
11:33:23	3	correct?	
11:33:24	4	A. I have to correct that.	
11:33:27	5	When I said that at my deposition, I	
11:33:28	6	misspoke. That one at Harvard was the two-layer	
11:33:33	7	laminate, which had LS on one side and Confor on	
11:33:38	8	the other; and I believe that you have now another	
11:33:42	9	test from Harvard that is the three-layer laminate,	
11:33:49	10	which tested essentially the same.	
11:33:54	11	Q. The test which is the subject of Exhibit	
11:33:59	12	129 predated the tests on the three-layer laminate	:
134:03	13	that you are talking about?	
11:34:04	14	A. Yes.	
11:34:09	15	Q. In your mind, the three-layer laminate foam	
11:34:28	16	and the two-layer laminate foam, both of which have	
11:34:32	17	Confor and LS foam, are substantially equivalent to	
11:34:37	18	a one-layer foam of EP made by Lendell?	
11:34:42	19	Have I got it right?	
11:34:44	20	A. You have it right, but it's not just in my	
11:34:48	21	mind. In reality, the tests show that they are	
11:34:51	22	substantially equivalent.	
11:34:53	23	Q. So "substantially equivalent," to you, when	
11:34:57	24	you say it that way, references the ability of the	

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135:01	1	foam to absorb impact?	53
11:35:04	2	A. No. There are other aspects as well.	
11:35:07	3	Q. What other aspects are you talking about	
11:35:10	4	that are set forth in this report?	
11:35:13	5	A. Okay. Basically I am not talking about	
11:35:17	6	other aspects that are set forth in that report.	
11:35:20	7	I believe you asked me the question:	
11:35:22	8	Are there other elements? There are other elements	
11:35:24	9	that do make them substantially equivalent.	
1 1:35:27	10	Q. And what are the other elements that make	
11:35:29	11	them substantially equivalent?	
11:35:31	12	A. Basically, as we know, I invented the	
135:36	13	encapsulated hip protector in 1995, and I have a	
11:35:40	14	lot of experience with this product category, and	
11:35:48	15	what makes them substantially equivalent is that	
11:35:51	16	the pads that are the subject of these tests are	
1 1:35:54	17	biomechanically very similar on their impact	
11:36:00	18	attenuation and that they are encapsulated foam	
11:36:07	19	pads, are launderable to one degree or another, and	
11:36:10	20	presently launderable up to 250 degrees.	
11:36:13	21	Q. So, was the foam which is the subject of	
1 1:36:21	22	129 launderable up to 250 degrees?	
11: 36:27	23	A. No.	
11:36:33	24	Q. The Confor foam let me back up.	

			54
136:38	1	The foam which was the subject of	
1 1:36:39	2	Exhibit 129 was the two-layer laminate, which was	
1 1:36:45	3	LS foam and Confor foam, right?	
11:36:51	4	A. Correct.	
1 1:36:53	5	Q. That's the foam that had to be removed from	
11:36:56	6	the product in order to be washable, right?	
1 1:36:58	7	A. No. That the one you mentioned was	**************************************
11:37:02	8	encapsulated.	
1 1:37:18	9	Q. The foam which is the subject of Exhibit	
11:37:28	10	129 was encapsulated?	
11:37:30	11	A. Yes.	
11:37:32	12	Q. That's the foam that you testified in your	
1:.37:56	13	previous deposition that's not satisfactory	
11:37:59	14	laundry-wise, right?	
11:38:00	15	A. That's correct.	
11:38:10	16	Q. So the subject the foam which is the	
11:38:15	17	subject of Exhibit 129 that had the launderability	
11:38:22	18	problems you are saying is substantially equivalent	
11:38:25	19	to the foam you are using now?	
11:38:26	20	MR. DAILEY: Objection.	
11:38:27	21	A. No, I'm not saying that.	
11:38:28	22	I am saying that the foam we use now	
11:38:31	23	I am not saying that the foam that we use now I	
11:38:34	24	am saying the product we use now is substantially	
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12:38:36	1	equivalent to the product of that test, but it's
11:38:40	2	improved.
11:38:41	3	Q. So one of the things that make it
11:38:51	4	substantially equivalent is its ability to reduce
11:38:57	5	the force of an impact, right?
11:38:59	6	A. That's correct.
11:38:59	7	Q. That's one thing?
11:39:00	8	A. Right.
11:39:00	9	Q. And the other thing that makes it
11:39:01	10	substantially equivalent is the launderability?
1 1:39:12	11	A. That's right.
11:39:13	12	Q. A few seconds ago you mentioned that there
139:15	13	was another test from Harvard.
11:39:19	14	Did I understand you correctly?
11:39:22	15	A. The next test was on the three-layer
11:39:27	16	laminate, and it turned out to be substantially the
1 1:39:30	17	same result as that one.
11:39:32	18	Q. When was that test performed, do you
11:39:36	19	remember?
11:39:36	20	A. I am not sure. '97, '98, '99.
11:39:40	21	Q. So how long did you use the two-layer
11:40:08	22	laminate which was the subject of the test in
11:40:09	23	Exhibit 129?
11:40:10	24	A. About four months.

56 So the test which is the subject of, or I $1 \pm :40:16$ 1 ο. should say, the foam, rather, that is the subject 11:40:33 2 of 129 was performed in or about April of '96, 11:40:35 3 11:40:41 4 correct? That's correct. 11:40:41 5 Α. 11:40:43 And you used that foam until approximately 6 11:40:47 what month? 7 Did you stop using it in 1996? 11:40:48 8 11:40:50 Α. I started using it in this encapsulated 9 form at the end of '95, and discontinued using it 11:40:55 10 11 right about the time of that test, probably, my 11:40:59 11:41:02 12 best recollection. So then you used the three-layer laminate $1 \pm .41 : 02$ 13 ο. foam for, I believe you said, up until 2000? 11:41:06 14 Α. That's right. 11:41:11 15 But you had it tested sometime around in 11:41:11 16 Q. '98 or the '99? 11:41:15 17 That's correct. Α. 11:41:17 18 11:41:18 19 And according to your best recollection, 0. the impact absorption of the three-layer foam was 11:41:22 20 approximately the same as the two-layer --21 11:41:26 Surprisingly, it was just about the same. 11:41:29 22 Α. I thought it would be better, but it was not. 11:41:32 23 Let me have you take a look at a document 11:41:34 24 0.

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141:52	1	which we will have marked as the exhibit next in
1 1:41:54	2	order, which I think is 130.
11:41:58	3	EXHIBIT NO. 130 MARKED
11:42:40	4	A. Okay.
11:42:40	5	Q. Have you had a chance to look at the
11:42:42	6	document marked Exhibit 130?
11:42:44	7	A. Yes.
11:42:44	8	MR. MORSEBURG: For the record, it has
11:42:45	9	Bates number HS2000151 through HS2000152 in the
11:42:52	10	lower right-hand corner.
11:42:54	11	Q. Have you ever seen Exhibit 130 before?
11:42:55	12	A. Yes, I have.
142:57	13	Q. What is it?
11:42:58	14	A. This is a test I had done at the University
11:43:01	15	of Tampere in 2000.
11:43:10	16	Q. It looks from the report that you had five
11:43:16	17	separate foams tested?
11:43:17	18	A. That's correct.
11:43:19	19	Q. And one of them is designated LS/CB, and I
11: 43:25	20	note that one of the foams that you were using
11:43:29	21	previously in connection with your product was EAR
11:43:38	22	Specialty Composite foam designated LS, and I see
11:43:41	23	this one is called LS/CB.
11:43:48	24	Is that an EAR foam?

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1_:43:50	1	A. Yes.	30
11:43:50	2	Q. Is the next one as well, the LS/CF an EAR	
11:43:55	3	foam?	
11:43:55	4	A. Yes, it is.	
11:43:55	5	Q. How about the final three: CB, the CF and	
11:43:58	6	the BM?	
11:43:59	7	A. Those CB and CF are Lendell CB is	
11:44:05	8	Lendell and CF is EAR and vinyl nitrile I think I	
11:44:12	9	got from Rubber Tex.	
11:44:21	10	Q. What's the designation "CB" stand for?	
11:44:37	11	A. I don't know. That's the manufacturer's	
11:44:42	12	code.	
144:44	13	Q. The same thing with CF, it's a manufacturer	
11:44:48	14	code?	
11:44:49	15	A. No. "CF" stands for Confor.	
11:44: 52	16	Q. Are any of the foams which are the subject	
11:45:03	17	of the test that is reported in Exhibit 130 a foam	
11:45:11	18	that Posey uses or has used in connection with its	
11:45:16	19	products?	
11:45:16	20	A. No, not that I'm aware of.	
11:45:28	21	Q. Did you earlier say that the Posey used	
11:45:30	22	Confor foam in its products?	
11:45:33	23	A. It's a different grade.	
11:45:36	24	Q. How do you know that?	
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59 11:45:38 The color. 1 Α. 11:45:43 You think it's a different grade because 2 11:45:48 the color is different? 3 11:45:49 4 Α. I know it's a different grade because the color is different. 11:45:52 5 11:45:53 What grade -- let's just start with the 6 11:45:58 foam which is in the first column, LS/CB what grade 7 11:46:06 8 is that foam? That is a CB foam, not a Confor 11:46:09 foam. 9 You don't know what the "CB" stands 11:46:09 1.0 11:46:11 for? 11 11:46:11 12 Α. No. The LS/CF, what grade is that foam? 1..46:12 13 0. The foams are colored by their indentation 11:46:16 14 Α. load deflection, and I believe the indentation load 11:46:24 15 11:46:34 deflection as they index it was -- this is a CF 16 Confor 45 blue -- Confor 40, I think. It's either 11:46:35 17 11:46:44 40 or 45. I don't know which one it is. 18 11:46:51 19 The Lendell foam, which is the subject of Q. 11:46:59 20 the third column down, CB, is that the EP foam that 11:47:06 21 you use now? 11:47:07 22 Α. It's a viscoelastic foam with very No. 11:47:15 23 similar properties, but it is not exactly the same 11:47:20 formulation. 24

·::47:22	1	Q. And the foam which is the subject of the
		_
11:47:23	2	next column, which is CF, and you said that is an
11:47:30	3	EAR Confor foam.
11:47:31	4	What grade is that one?
11:47:32	5	A. It's the blue, and I am not sure what the
11:47:35	6	value is, whether it is 40 or 45.
11:47:37	7	Q. So was the second column either 40 or 45;
11:47:41	8	and if it was 40, then the fourth column was 45?
11:47:46	9	A. They are one in the same, yes.
11:47:51	10	Q. What was the difference between LS/CF and
11:47:56	11	the CF?
11:47: 56	12	A. The CF was half an inch unto itself, and
148:11	13	the LF/CS was an eighth of an inch of LS and three-
1 1:48:17	14	eighths of an inch of CF.
11: 48:17	15	Q. Okay. The LS/CF was a laminate?
11:48:24	16	A. Yes.
11:48:39	17	Q. And the LS/CB, which is the subject of the
11:48:42	18	first column, was that also a laminate?
11:48:44	19	A. Yes.
11:48:45	20	Q. Were any of the foams which are the subject
11:48:58	21	of Exhibit 130 used in any HipSaver products?
11:49:04	22	A. Yes.
11:49:05	23	Q. Which one?
11:49:06	24	A. LS/CF, that's a laminate pad, that would be

Edward L. Goodwin, vol. 3 CONFIDENTIAL - ATTORNEYS' EYES ONLY

03/03/2006

1_:49:16	1	the same construction that was tested at Harvard,
11:49:22	2	and the LS/CB
11:49:37	3	Q. And the LS/CB, I'm sorry, did you finish
11:49:42	4	your answer?
11:49:43	5	A. No. The LS/CB I used for about four
11:49:50	6	months, until the manufacturer discontinued
1 1:49:52	7	production on that particular model.
11:49:55	8	Q. Who did the laminations of the two foams?
11:50:04	9	A. I did.
11:50:06	10	Q. Let me see if I understand it.
11:50:32	11	You had at some point a two-layer
11:50:36	12	laminate foam. Was that the LS/CB?
150:43	13	A. CF. LS/CF.
11:50:49	14	Q. Okay. That's the one that you were using
11: 50:52	15	in 1996, and you discontinued right around the time
11:50:58	16	of the first Harvard test we talked about, which is
1 1:51:01	17	Exhibit 129?
11:51:02	18	A. I didn't really discontinue it. I added
11:51:05	19	another layer of lamination to it.
11:51: 07	20	So essentially the component was
11:51:10	21	still there, but it was enhanced.
11:51:11	22	Q. Okay. In relation to that time frame, when
11:51:13	23	did you use the laminate, which is the LS/CB, which
11:51:18	24	is in the first column?

151:19	1	A. That would have been in early 2000, the	62
11:51:23	2	spring of 2000, actually.	
11:51:25	3	Q. So, you went from a let me just see if I	
11:51:40	4	have it down.	
11:51:41	5	You went from a two-layer laminate,	
11:51:43	6	which was the LS/CF, to a three-layer laminate of	
11:51:49	7	LS/CF, and back to a two-layer laminate which was	
11: 51:53	8	LS/CB?	
1 1:51:54	9	A. I'm sorry. If I said the LS/CB I am not	
11:52:01	10	sure I said what I should have said.	
11:52:03	11	The CB is what I used. I didn't use	
11:52:05	12	the LS/CB.	
152:07	13	Q. Okay.	
11:52:09	14	A. I am not sure what I said or what you	
11:52:11	15	asked, but what I do know is I never used LS/CB. I	
1 1:52:15	16	used just the CB, which is a very comparable foam	
11:52:17	17	to the EP 4.	
11:52:20	18	Q. All right. Okay.	
1 1:52:24	19	When you said you used the foam for	
11:52:26	20	about four months until the manufacturer	
11:52:29	21	discontinued it in early 2000, you were talking	
11:52:32	22	about the CB foam, the Lendell CB foam, as opposed	
11:52:35	23	to the ERA foam?	
11:52:36	24	A. Right.	
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/:> 12.52:37	1	Q. I got it.	63
11:52:53	2	Did you compare the test which was the	
11:52:55	3	subject of Exhibit 130 with the test which was the	
11:52:58	4	subject of Exhibit 129?	
11:53:00	5	A. I was aware of the fact that the test for	
11:53:07	6	the laminate pad came out better at the University	
11:53:13	7	of Tampere and that was the extent of what I	
11:53:26	8	thought about for a comparison.	
11:53:28	9	Q. Did you ask anybody at the Tampere	
11:53:32	10	university why their test results were so different	
11:53:36	11	from the tests which had been performed by	
11:53:41	12	Dr. Hayes and reported in Exhibit 129?	
153:44	13	A. No. I didn't ask anybody, the reason being	
11:53:47	14	that the state of the art for biomechanical testing	
1 1:53:53	15	of hip protectors was evolving very rapidly at this	
11:53:58	16	time in terms of what would be the indices of the	
11:54:02	17	bone fragility, and what would be a proper impact	
11:54:05	18	force, and what is the proper soft-tissue modeling	
11:54:08	19	and all of those issues.	
11:54:09	20	And my assumption was that the	
11:54:11	21	University of Tampere, because it was more	
11:54:16	22	contemporary at that time, meaning that it was	
11:54:19	23	subsequent to the Hayes work by six or seven years,	
11:54:23	24	and they had done so much work on hip fractures and	

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.54:32	1	hip protectors they are actually used as the	64
11:54:33	2	sort of benchmark for biomechanical testing for a	
11:54:38	3	number of years.	
11:54:39	4	Q. I'm sorry, maybe I missed it.	
11:54:53	5	A. I did not ask anybody about it.	
11:55:03	6	MR. MORSEBURG: Let me have marked as	
11:55:04	7	exhibit next in order a two-page document with	
11:55:09	8	Bates numbers HS2000153 through 000154.	
11:55:17	9	EXHIBIT NO. 131 MARKED	
11:55:31	10	THE WITNESS: Can we take a break?	
11:55:32	11	MR. MORSEBURG: Yes.	
11:55:33	12	THE VIDEOGRAPHER: This marks the end	
1. 55:34	13	of tape number one in the deposition of Edward L.	
11:55:42	14	Goodwin. The time is 11:55 a.m.	
12:03:09	15	(A recess was taken.)	
12:06:57	16	THE VIDEOGRAPHER: One second, please.	
12:07:04	17	Here begins videotape number two, day three, in the	
12:07:09	18	deposition of Edward L. Goodwin. Going on the	
12:07:12	19	record, 12:07 p.m.	
12:07:15	20	Q. Mr. Goodwin, before the break, we had	
12:07:18	21	marked as Exhibit 131 a two-page document, but	
12:07:21	22	before I ask any questions about that, let me go	
12:07:25	23	back one-half second.	
12:07:26	24	If you told me, I missed it. The foam	

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15:57:28	1	Q. When you say it's the validation page, is
1 3:57:31	2	it correct that this is again a page from your
13:57:34	3	Website?
1 3:57:34	4	A. Yes.
13:57:35	5	Q. It's dated 3/3/2006, do you see that in the
13:57:41	6	lower right-hand corner?
13:57:4 2	7	A. Yes.
1 3:57:43	8	Q. Is this a copy of the current Web page, or
13:57:47	9	at least the first section of the current Web page
1 3:57:49	10	on validation and testing?
13:57:50	11	A. Yes, it is.
13:57:53	12	Q. I am going to ask you at the same time to
57:56 د 1	13	look at a document that has been previously entered
1 3:57:58	14	in this case as the infamous Exhibit 1, which is
13:58:02	15	the cause of many of the disputes that
13:58:05	16	Mr. Morseburg and I have had before we bonded.
13:58:09	17	I will ask you to take a moment to look
13:58:16	18	at that document, and in particular, I am going to
13:58:19	19	direct your attention to the third page in Exhibit
13:58:25	20	1, which is Page 247 in the printed version.
13:58:44	21	Now, first let me direct your attention
13:58:46	22	to Exhibit 1, Dr. Burl's study, and the last
13:58: 53	23	sentence on Page 247 reads, "The average compliance
13:58:58	24	was 93 percent. (Range 67 to a hundred percent)."

ر 1ء:59:05	1	Did I read that correctly?	106
13:59:06	2	A. Yes.	
13:59:06	3	Q. Do you see that statement?	
13:59:07	4	A. Yes, I do.	
13:59:08	5	Q. If you go back and look at Exhibit 140, the	
1 3:59:15	6	page from your Website, I'm going to ask you to	
1 3:59:17	7	count down, one, two, three, four strike that.	
13:59:23	8	I can't count correctly today. It's the medication	
13:59:25	9	I'm under. Doug didn't ask me if I was under	
13:59:28	10	medication today.	
13:59:29	11	I am going ask you to count down, one,	
13:59:31	12	two, three lines and over to the right. It begins	
15:59:37	13	with the word "The."	
13:59:38	14	Do you see it?	
13:59:39	1 5	A. Yes.	
13:59:40	16	Q. "The study authors report an average 93	
13:59:43	17	percent compliance rate for the duration of the	
13:59:45	18	study."	
13:59:46	19	Did I read that correctly?	
13:59:47	20	A. Yes.	
13:59:47	21	Q. Is that a reference to Dr. Burl's study?	
13:59:51	22	A. It's a reference to Dr. Burl's study, but	
13:59:56	23	it's also a reference to more knowledge that we had	**************************************
13:59:57	24	obtained when we went to the Journal of American	the second secon

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107 Medical Directors presentation of Dr. Burl's study 15:59:58 1 approximately nine months before this. 14:00:03 2. Is this statement that -- on your 14:00:05 Okay. 3 Q. Website that the study authors report an average 93 14:00:11 4 compliance rate for the duration of the study an 14:00:16 5 accurate statement? 14:00:19 6 That is an accurate statement, but there is Α. 14:00:20 7 a more accurate statement that could be made about 14:00:21 8 14:00:23 9 this study. And what is that? Okav. 14:00:24 10 0. And that comes on Page 248, where it says 14:00:26 11 -- they excluded two people who didn't want to be 14:00:31 12 involved in the study. The average daily 14:00:33 13 compliance exceeded 95 percent. 14:00:35 14 So actually we have understated the 14:00:37 1.5 compliance that was obtained from habitual wearers 14:00:40 16 of the HipSaver during this study. 14:00:44 17 So, in fact, the more accurate statement 14:00:46 18 0. about compliance would have been, with respect to 19 14:00:49 folks who wore hip protectors for the entire 14:00:53 2.0 duration of the study, would have been a 95 percent 14:00:58 21 14:01:00 22 compliance rate --That's right. 14:01:00 23 Α. -- is that correct? Q. 14:01:01 24 11.

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14:01:01	1	A. That's correct.	
14:01:02	2	MR. MORSEBURG: I object. No	
14:01:04	3	foundation.	
14:01:05	4	MR. DAILEY: Okay.	
14:01:19	5	MR. MORSEBURG: Leading.	
14:01:20	6	Q. I may have put that away too quickly. Let	
14:01:29	7	me ask you again to just stay with Exhibit 140.	***************************************
14:01:38	8	Do you see the statement just below the	
14:01:41	9	statement I read earlier on Exhibit 140 where it	
14:01:44	10	says, "Equally important, there were 126 falls	
14:01:48	11	among the HipSaver wearers and no hip fractures"?	
14:01:53	12	A. Yes.	
14:01:54	13	Q. Did I read that correctly?	
14:01:55	14	A. Yes.	
14:01:57	15	Q. Was this important?	
14:01:58	16	A. Absolutely, it's important.	
14:02:03	17	The idea of hip protectors is to	
14:02:06	18	prevent hip fractures, and in 126 falls with no hip	
14:02:11	19	fractures, in this group of people who were	
14:02:14	20	selected for their multi-factual conditions	
14:02:18	21	predisposing them to a hip fracture, it's	
14:02:21	22	absolutely important.	
14:02:23	23	Aside from that, it's important because	
14:02:25	24	if there were the standard amount of hip fractures	
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109 14:02:28 in this population, which could be three or four, 1 14:02:31 2 then that put doubt on HipSaver as an effective 14:02:35 3 intervention. So it is important for the people that 14:02:36 4 were involved in the study, for the people that 14:02:37 5 14:02:39 were wearing it, but also from the validation 6 standpoint of the product, that no hip fractures 14:02:42 7 indicate that the product was effective during the 14:02:46 8 study, and that it achieved the whole idea of what 14:02:48 9 the product was all about, to prevent hip 10 14:02:50 fractures; and that's why it is important. 14:02:53 11 14.02:56 12 Thank you. Q. 14:03:18 I am going to ask the 13 MR. DAILEY: 14:03:20 stenographer to mark as the next exhibit in order a 14 physical exhibit, and there is only one copy of it. 14:03:24 15 EXHIBIT NO. 141 MARKED 14:03:28 16 MR. DAILEY: Don't wreck it. It's 14:03:45 17 already wrecked. Is this how you guys make your 14:04:00 18 14:04:04 19 products? Oh, man. 20 I am going to ask you to take a moment and 14:04:07 just review Exhibit 141. 14:04:17 21 Do you know what that is? 14:04:23 22 This here is a specimen of a Posey Hipster, 14:04:24 23 Α.

or the pad that was in one that was mistakenly sent

14:04:30

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03/03/2006

Edward L. Goodwin, Vol. 3 CONFIDENTIAL - ATTORNEYS' EYES ONLY

1 01 57	1		124
14:21:57	1	your testimony is?	
14:21:57	2	MR. DAILEY: Objection.	
14:21:58	3	A. I think if you look at the graphic, it	
14:22:04	4	says, "CDC minimum recommended wash temperature 160	
14:22:04	5	degrees."	
14:22:10	6	Now, that is the most explicit	
14:22:12	7	statement, take-home statement, that a person	
14:22:14	8	reading this could understand: that it's got to be	
14:22:18	9	a minimum of 160. So the range has to be higher	
14:22:22	10	than 160.	
14:22:23	11	Q. So you're intending by this statement, "CDC	
14:22:30	12	guidelines recommended wash temperature range," to	
14:22:34	13	convey the message that there is temperature of	
14:22:40	14	160, at a minimum, to something at a maximum, which	
14:22:43	15	is the CDC guideline recommended range, right?	
14:22:47	16	MR. DAILEY: Objection.	
14:22:48	17	A. The CDC doesn't have maximum. They have a	
14:22:50	18	minimum, and I am not intending anything here other	
14:22:54	19	than to tell the consumer that in order to be	
14:22:59	20	within the CDC guideline they have to be higher	
14:23:02	21	than 160, and that's what this graphic says, and	
L4:23:05	22	you're trying to put a cap on it that doesn't	
L4:23:07	23	exist.	
4:23:08	24	Q. In fact, the CDC guideline recommended wash	

Edward L. Goodwin, Vol. 3 CONFIDENTIAL - ATTORNEYS' EYES ONLY

03/03/2006

		135
1	ERRATA SHEET	
2	I, Edward L. Goodwin, do hereby certify	
3	that I have read the foregoing transcript of my	
4	testimony, and further certify that it is a true	
5	and accurate record of my testimony (with the	
6	exception of the corrections listed below):	
7	Page Line Correction	
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20	Signed under the pains and penalties of perjury	
21	this, day of, 2006.	
22		
23		
24	Edward L. Goodwin	

Edward L. Goodwin, Vol. 3 CONFIDENTIAL - ATTORNEYS' EYES ONLY

		136
1	COMMONWEALTH OF MASSACHUSETTS)	
2	SUFFOLK, SS)	
3		
4	I, Deborah L. Roth, and Notary Public in and for	
5	the Commonwealth of Massachusetts, do hereby	
6	certify that there came before me on March 3,	
7	2006, the person hereinbefore named, who was by me	
8	duly sworn to the truth concerning any knowledge	
9	in this cause; that that person was thereupon	
10	examined under oath, and the examination reduced	
11	to typewriting; and that the deposition is a true	
12	record of the testimony given by the witness.	
13	I further certify that I am neither related to nor	
14	employed by any attorney or counsel employed by	
15	the parties hereto or financially interested in the	
16	action.	
17	In witness whereof, I have hereunto set my hand	
18	this 11th day of March 2006.	
19	1 1 1 1 0 11 00000000000000000000000000	
20	Deborah J. Roth CERTIFIED TRANSCRIPT LEGALINK BOSTON	
21	DEBORAH ROTH, Notary Public	
22	My commission expires: 2/7/08	
23		
24		

EXHIBIT 8

CONFIDENTIAL, FILED UNDER SEAL

Exhibit 9

Case 1:05-cv-10917-PBS Document 164 Filed 12/12/2006 Page 1 of 5

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

THE HIPSAVER COMPANY, INC.,) Civil Action No. 05-10917 PBS
Plaintiff,)
v.)
J.T. POSEY COMPANY,)
Defendant.)
AND RELATED COUNTERCLAIM.	

DECLARATION OF ERNEST POSEY IN SUPPORT OF MOTIONS OF J.T. POSEY COMPANY FOR SUMMARY JUDGMENT ON HIPSAVER'S CLAIMS AND FOR PARTIAL SUMMARY JUDGMENT ON COUNT I OF POSEY'S COUNTERCLAIMS

I, Ernest Posey, declare:

- 1. I am the President of J.T. Posey Company ("Posey"), a defendant and counterclaimant in this matter. I have personal knowledge of the facts set forth below and, if called as a witness and properly sworn, I could and would testify thereto from my own personal knowledge. I make this declaration in support of Posey's motion for summary judgment on the claims of defendant The HipSaver Company, Inc. ("HipSaver") and in support of Posey's motion for partial summary judgment in its favor on Count I of its counterclaims.
- 2. During the time of the first false advertising lawsuit between Posey and HipSaver, I was also the President of Posey. That suit was *HipSaver Co., Inc. v. J.T. Posey Co.*,

Case 1:05-cv-10917-PBS Document 164 Filed 12/12/2006 Page 2 of 5

USDC, Dist. of Mass., Case No. 04-11294 PBS ("Posey I"). I received the complaint in that suit on or about June 10, 2004. The complaint in Posey I expressly made reference to some alleged false advertising by Posey that was based upon some hip protector testing that was performed in about 2003 by a UCLA graduate student named Bimal Gandhi. This testing resulted in a writing known as the "White Paper." Prior to that suit, Posey had placed in literature statements regarding some impact testing that was performed for Posey by a testing laboratory named Garwood Laboratories, Inc. ("Garwood Testing").

3. On or about September 22, 2004, I executed a written agreement settling Posey I.

A true and correct copy of that agreement is attached as Exhibit 3 to the accompanying

Appendix. Paragraph 11 of the Settlement Agreement provides:

Except for the obligations contained in this Agreement, HipSaver releases Posey, and all of its officers, directors, employees, agents, representatives, dealers, distributors, shareholders, attorneys, predecessors, successors, assigns, affiliates, related companies, or corporations connected with them from any and all claims, liabilities or causes of action, known or unknown, fixed or contingent, which arise from or are related to the false advertising claims under 15 U.S.C. § 1125, 1117 and G.L. c.93A, §§ 2, 11 which were asserted or which could have been asserted in the Action for conduct which occurred prior to the date of this Agreement.

- 4. When I signed the settlement agreement, I understood that Posey was being released from all potential claims by HipSaver related to any false advertising claims based upon any statements or claims that Posey had made in its advertising, including its brochures, flyers, instruction sheets, and its Internet website. I also understood that Posey was releasing HipSaver from all similar claims and that, going forward, both parties were going to be able to continue making the advertising claims and statements they had made in the past, except for references to the White Paper, and that neither side was going to be able to bring any lawsuits contesting those claims.
- 5. I also understood the language releasing Posey from claims "known or unknown, fixed or contingent, which arise from or are related to the false advertising claims under

15 U.S.C. § 1125, 1117 and G.L. c.93A, §§ 2, 11 which were asserted or which could have been asserted in the Action for conduct which occurred prior to the date of this Agreement" to mean that all claims for false advertising which could have been asserted before the date of the agreement were being released.

- 6. For example, at the time I signed the settlement agreement, both Posey and HipSaver were making certain statements on their Internet web pages and in their literature. In Posey's case, those statements mirrored the statements in some of Posey's printed materials that dated as far back as 2001. I understood that, except for deleting any references to the "White Paper" in its advertising, the release meant that Posey could continue its website unchanged and reprint all statements in its literature as they were without having to be concerned about further legal action from HipSaver, just as HipSaver could continue its website as it was without having to be concerned about further legal action from Posey.
- 7. As part of the settlement of Posey I, Posey paid HipSaver the sum of \$360,000. Suffice it to say, I would never have agreed to permit Posey to enter into the settlement agreement if I had thought that HipSaver would be able to dismiss its claims in Posey I and then turn around and sue Posey again in connection with advertising statements which had appeared in Posey's literature prior to the settlement, such as the statements Posey had been making for three years about the Garwood testing.
- 8. Notwithstanding the foregoing, I did not understand that the release allowed either party the unlimited right to make any product claim it wanted after the settlement. That is to say, I understood that even though the parties were permitted to continue making the statements they had been making in the same context, the release would not permit either party to make substantial changes to the claims in their advertisements and then to attribute these new claims to previous tests or studies.

I declare under penalty of perjury under the laws of the United States and under the laws of the State of Massachusetts that the foregoing is true and correct and that this Case 1:05-cv-10917-PBS Document 164 Filed 12/12/2006 Page 4 of 5

declaration was executed by my hand this 11th day of December, 2006 at Arcadia,

California.

/s/ Ernest Posey

Ernest Posey

Case 1:05-cv-10917-PBS Document 183-10 Filed 01/08/2007 Page 6 of 6

CERTIFICATE OF SERVICE

I certify that this document has been filed through the Electronic Case Filing System of the United States District Court for the District of Massachusetts and will be served electronically by the court to the Registered Participants identified in the Notice of Electronic filing.

December 11, 2006

/s/ Donald K. Piper
Donald K. Piper

Exhibit 10

EXHIBIT B

Special Announcement: HipSaver® and Posey Hipster® brand Hip Protectors

In the fall of 2003, Posey began distributing an article (also known as the "White Paper") entitled "A Solution to Hip Fractures Using Performance Tested Hip Protectors," In its catalogs and newsletters, Posey included statements derived from the White Paper and bar charts comparing the relative effectiveness of Posey's Hipsters.

The White Paper was written by a UCLA graduate student working on his Master's Thesis. UCLA did not sponsor, authorize, or endorse the tests or the results reported in the White paper or the Master's Thesis.

The HipSaver Company, Inc. challenged the accuracy of the White Paper and the statements and bar charts in Posey's catalogs and newsletters. HipSaver's claims included: (a) a flawed testing methodology used by the graduate student; (b) testing of some products which were no longer offered in the marketplace; and (c) test conclusions which were subject to unreliable or false interpretation.

The HipSaver Company retained Wilson C. Hayes, PhD, a recognized biomechanical engineering expert, to review the White Paper, the graduate student's thesis, and Posey's advertising. Dr. Hayes determined that the research is not reliable and cannot sustain any of the claims in the White Paper and our advertising with reasonable certainty.

Posey values its hard-earned reputation and does not advocate the use of any material that may be inaccurate or out of date, and expressly regrets comparisons with HipSaver products and confusion this may have caused in the marketplace.

Posey has eliminated the bar charts and all statements based on the White Paper from its catalogs.

If by chance you have a copy of the White Paper or any advertising material referring to testing at UCLA, please do not use it or to rely on any statements in it.

If you have any questions about anything in this announcement, please contact Posey at [telephone number]

EXHIBIT B (page 1 of 1)

Deposition of Victoria Lewis
Date December 15, 2005
Plaintiff's Exhibit 99

For Indentification

Denise Herft, CSR 12983

Exhibit 11

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into between The HipSaver Company, Inc. ("HipSaver") and J.T. Posey Company, Inc. ("Posey") with reference to the following facts:

RECITALS

- A. HipSaver has filed an action in the United States District Court for the District of Massachusetts entitled *The HipSaver Company, Inc. v. J.T. Posey Company, Inc.*, as Civil Action No. 04-11294 PBS (the "Action"), in which HipSaver accuses Posey among other things of having violated the Lanham Act and the Massachusetts Unfair or Deceptive Business Practices Act by disseminating certain materials, including a document entitled "A Solution to Hip Fractures Using Performance Tested Hip Protectors" (the "White Paper") and including in Posey catalogs and promotional materials certain bar charts comparing the relative effectiveness of hip protectors (the "Bar Charts") and statements derived from the White Paper.
 - B. Posey denies the allegations asserted by HipSaver in the Action.
- C. Posey filed an answer and counterclaim in the Action in which Posey asserts among other things that HipSaver has made false representations about Posey products on HipSaver's website
 - D. HipSaver denies the allegations asserted by Posey in the Counterclaim.
- E. The Parties desire to settle all disputes among them concerning or in any way related to the Action.

NOW, THEREFORE, in consideration of the promises, covenants and conditions set forth in this Agreement, the Parties hereto agree as follows:

- 1. Posey shall pay to HipSaver the sum of \$360,000.00 by check payable to The BROMBERG SUNSTEIN LLP Client Account to be delivered to BROMBERG SUNSTEIN within fourteen (14) days of the filing of the Stipulation for Dismissal of the Action as set forth in paragraph 12 below (the "Stipulation for Dismissal").
- 2. Posey shall not distribute the White Paper or make any advertising claims based on or derived from the White Paper.

- 3. Posey shall permanently comply with the terms of the Undertaking filed in the Action by Posey on August 26, 2004, a copy of which is attached hereto as Exhibit "A".
- 4. In all future catalogs and other promotional materials Posey shall eliminate the Bar Charts and statements based on or derived from the White Paper and references to UCLA.
- 5. Within ten days from the filing of the Stipulation for Dismissal Posey shall provide all its sales representatives, distributors, and dealers who have purchased or sold Posey Hipster hip protectors at any time since January 1, 2001 a copy of the "Special Announcement: HipSaver® and Posey Hipster® brand Hip Protectors" a copy of which is attached hereto as Exhibit "B" (the "Special Announcement").
- 6. Within ten days from the filing of the Stipulation for Dismissal Posey shall post a link to a copy of the "Special Announcement: HipSaver and Posey Hipster brand Hip Protectors" on the first screen of the home page of the Posey web site immediately below the heading, "Resources for Healthcare Professionals". This posting shall continue until Posey has published and distributed its next editions of its Posey's "full line" catalogs and its "falls management and bed safety products" catalogs.
- 7. When Posey next distributes any of its annual catalogs advertising hip protectors, including Posey's "full line" catalogs and its "falls management and bed safety products" catalogs, it shall include therewith in the same envelope a copy of the Special Announcement: HipSaver and Posey Hipster brand Hip Protectors".
- 8. In the event of any further comparative testing of Posey and HipSaver products by either party, neither party shall make commercial advertising use of the results or analysis related to such testing without first giving the other party at least thirty (30) days advance written notice of the results or analysis.
- This Agreement represents the compromise of disputed claims. Nothing contained here may be construed as an admission of wrongdoing or liability by any party.
- 10. Except for the obligations contained in this Agreement, Posey releases HipSaver, and all of its officers, directors, employees, agents, representatives, dealers, distributors, shareholders, attorneys, predecessors, successors, assigns, affiliates, related . companies, or corporations connected with them from any and all claims, liabilities or

Page 4 of 10

causes of action, known or unknown, fixed or contingent, which arise from or are related to the false advertising claims under 15 U.S.C. §§ 1125, 1117 and G.L. c.93A, §§ 2, 11 which were asserted or which could have been asserted in the Action for conduct which occurred prior to the date of this Agreement.

- Except for the obligations contained in this Agreement, HipSaver releases Posey, and all of its officers, directors, employees, agents, representatives, dealers, distributors, shareholders, attorneys, predecessors, successors, assigns, affiliates, related companies, or corporations connected with them from any and all claims, liabilities or causes of action, known or unknown, fixed or contingent, which arise from or are related to the false advertising claims under 15 U.S.C. §§ 1125, 1117 and G.L. c.93A, §§ 2, 11 which were asserted or which could have been asserted in the Action for conduct which occurred prior to the date of this Agreement.
- 12. Concurrently with the counter-execution of this Agreement the Parties agree that their respective counsel will execute and file a Stipulation for Dismissal of the Action with prejudice substantially in the form of Exhibit "C" attached.
- HipSaver acknowledges and agrees that it will not initiate any legal action against Vijay Gupta, Bimal P. Gandhi, or the University of California for any claim related to the false advertising claims under 15 U.S.C. §§ 1125, 1117 and G.L. c.93A, §§ 2, 11 which were asserted or which could have been asserted in the Action for conduct which occurred prior to the date of this Agreement.
- The terms of this Agreement shall remain confidential except that they are binding and enforceable and are admissible for the purposes of enforcement. In addition, either party may truthfully report that the Action has been settled to the mutual satisfaction of the Parties. It is expressly understood and agreed that HipSaver may distribute and publish the "Special Announcement: HipSaver and Posey Hipster brand Hip Protectors" and may state that Posey will distribute that document in its new catalogs and to its sales representatives, distributors, and dealers. Except as provided in this paragraph, no Party shall, without notice to and the prior written consent of the other Party, disclose any of the terms and conditions of this Agreement to any person or entity, including, without limitation, to any customers or potential customers of a Party, provided, however, that any Party may disclose such information to the extent required

by law or order of a court or government agency; and the Parties may inform their attorneys and independent public accountants of the terms and conditions of this Agreement.

- 15. Each party shall bear its own costs, expenses and attorneys' fees in connection with the Action and the negotiation, preparation, and execution of this Agreement.
- 16. Any notices or other communications under this Agreement shall be in writing, and shall be sent by facsimile and/or by email attachment, with a copy by hand-delivery or overnight courier service, as follows:

Notice Addresses:

To HipSaver:

The HipSaver Company, Inc. 7 Hubbard Street Canton, Massachusetts 02021 Attention: Edward L. Goodwin Fax: 1.781.821.6514

With a copy to:

BROMBERG SUNSTEIN LLP 125 Summer Street Boston, Massachusetts 02110-1618 Attention: Edward J. Dailey, Esq. Fax: (617) 443-0004

To: Posey:

J.T. Posey Company 5635 Peck Road Arcadia, CA 91006 Attention: Ernest Posey Fax: (626) 443-9886

With a copy to:

SHELDON & MAK. 225 South Lake Avenue, 9th Floor Pasadena, California 91101 Attention: Jeffrey G. Sheldon, Esq. Fax: (626) 795-6321

17. The Parties, and each of them, acknowledge that they have completely read the terms of this Agreement, and fully understand the terms and consequences of this Agreement. All Parties further acknowledge that they have been represented by

counsel with respect to the negotiation and execution of this Agreement and that their counsel has explained the terms and the significance of this Agreement.

- 18. The failure of any party to insist upon the strict compliance by any other party to this Agreement of the performance of any covenant, condition or promise herein shall not invalidate this Agreement nor shall any such failure be construed as a waiver or relinquishment of the performance of any other covenant, condition or promise in this Agreement.
- 19. This Agreement is the entire agreement between and among the Parties hereto with respect to the subject matter set forth herein.
- Each party has cooperated in the drafting and preparation of this Agreement. Hence, neither this Agreement nor any part of it shall be construed against either party merely because such party may have drafted all or part of it.
- 21. The Parties to this Agreement, and each of them, agree to perform such further and other acts and to execute and deliver such further and other documents as may be reasonably necessary to carry out the provisions of this Agreement.
- 22. Each party hereto represents and warrants that it has full power and authority to enter into this Agreement and to perform any and all transactions or other matters contemplated to be performed under this Agreement.
- This Agreement may be amended or modified only by a written instrument signed by all of the Parties.
- 24. This Agreement shall be binding on and shall inure to the benefit of the Parties hereto, and their respective officers, directors, shareholders, legal representatives, assignees and successors-in-interest.
- This Agreement may be executed by facsimile and in counterparts all of which taken together shall constitute a single instrument.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date set forth next to their respective signatures below.

THE HIPSAVER COMPANY, INC.

J.T. POSEY COMPANY, INC.

By: Edward Joseph By: Em TM Posey

Edward L. Goodwin, President Its: <u>Greadent</u>	Its: President
Dated: 9/22/04, 2004	Dated: 9/21/2064, 2004
APPROVED AS T	TO FORM:
BROMBERG SUNSTEIN LLP	SHELDON & MAK PC
By: nwood nil	By: Noto Saller
Edward J. Dailey Attorneys for HipSaver	Jeffrey G. Wheldon Attorneys for Posey
Dated: 9-01-04 ,2004	Dated: 9 (1) ,2004

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

·	Civil Action No. 04-11294-PBS
HIPSAVER COMPANY, INC.,)
Plaintiff,)
v.	<u>}</u>
J.T. POSEY COMPANY,	,
Defendant.))

UNDERTAKING BY DEFENDANT J.T. POSEY COMPANY

During the pendency of the above action Posey undertakes and agrees as follows:

- 1. Posey has discontinued distribution of the White Paper authored by Bimal P. Gandhi ("White Paper");
- 2. Posey has discontinued distribution of catalogs and all other materials containing information derived from the White Paper;
- 3. Posey has instructed all its employees, sales representatives, and distributors who have purchased Hipsters since 2001, to discontinue all reference to the White Paper and information derived from the White Paper, nor represent that its hip protectors have been validated by scientific research at UCLA, in communications with

EXHIBIT A (page 1 of 2) customers or potential customers, including written correspondence, emails, telephonic or face-to-face conversations, sales pitches, and the like;

- 4. Posey will not include the White Paper or information derived from the White Paper in any future catalogs, brochures, or other advertising materials.
- 5. Posey will not represent that its hip protectors have been validated by scientific research at UCLA.

This undertaking is not made as any admission of liability or wrongdoing, but because Posey values its reputation, and does not engage in activities that are in any way questionable.

Dated: August 26, 2004

J.T. POSEY COMPANY

By: s/Ernest M. Posey/ Ernest M. Posey

EXHIBIT A (page 2 of 2)

EXHIBIT B

Special Announcement: HipSaver® and Posey Hipster® brand Hip Protectors

In the fall of 2003, Posey began distributing an article (also known as the "White Paper") entitled "A Solution to Hip Fractures Using Performance Tested Hip Protectors," In its catalogs and newsletters, Posey included statements derived from the White Paper and bar charts comparing the relative effectiveness of Posey's Hipsters.

The White Paper was written by a UCLA graduate student working on his Master's Thesis. UCLA did not sponsor, authorize, or endorse the tests or the results reported in the White paper or the Master's Thesis.

The HipSaver Company, Inc. challenged the accuracy of the White Paper and the statements and bar charts in Posey's catalogs and newsletters. HipSaver's claims included: (a) a flawed testing methodology used by the graduate student; (b) testing of some products which were no longer offered in the marketplace; and (c) test conclusions which were subject to unreliable or false interpretation.

The HipSaver Company retained Wilson C. Hayes, PhD, a recognized biomechanical engineering expert, to review the White Paper, the graduate student's thesis, and Posey's advertising. Dr. Hayes determined that the research is not reliable and cannot sustain any of the claims in the White Paper and our advertising with reasonable certainty.

Posey values its hard-earned reputation and does not advocate the use of any material that may be inaccurate or out of date, and expressly regrets comparisons with HipSaver products and confusion this may have caused in the marketplace.

Posey has eliminated the bar charts and all statements based on the White Paper from its catalogs.

If by chance you have a copy of the White Paper or any advertising material referring to testing at UCLA, please do not use it or to rely on any statements in it.

If you have any questions about anything in this announcement, please contact Posey at [telephone number]

EXHIBIT B (page 1 of 1)

Deposition of Victoria Lewis

Date <u>December 15, 2005</u>

Plaintiff's Exhibit 99

For Indentification Denise Herft, CSR 12983

Exhibit 12

CONFIDENTIAL

Taylor, Lisa

From: Hynous, Liz

Sent: Friday, October 15, 2004 12:50 PM

To: Smit

Smith, Joyce

Cc: Wenz, Connie; Hollins, Sharon

Subject: FW: Posey Hipsters brand hip protectors

FYI - Connie I did not see your name on the message below. Thanks Liz

-----Original Message-----From: Ferguson, Mike

Sent: Thursday, October 14, 2004 6:20 AM

To: Parker, Bonnie; Gerharter, Paul; Hynous, Liz; Orlowski, Annette; Tidwell, Suzanne

Subject: FW: Posey Hipsters brand hip protectors

FYI...Posey's response to the lawsuit settlement.

Mike

----Original Message-----

From: Gary Platzman [mailto:gplatzman@posey.com]

Sent: Wednesday, October 13, 2004 5:37 PM

To: Cusack, Bill

Cc: Emie Posey; Joe Cain

Subject: Posey Hipsters brand hip protectors

Bill,

The following is a summary of the situation with the Hipsters from Ernie Posey.

Thank you.

Gary Platzman

In 2003 the Posey Company was approached by a graduate student in Biomechanical Engineering at the University of California at Los Angeles with a proposal to do a Masters Thesis titled "A Solution to Hip Fractures Using Performance Tested Hip Protectors." He proposed to do a literature survey on previous testing and then build the equipment necessary to complete the testing of the various products available on the market at that time. His testing was based on the information learned in the literature survey.

Posey gave UCLA an unrestricted grant to build the testing equipment and complete the research by the graduate student. UCLA did not sponsor or endorse the tests or the results reported in the Masters Thesis or the resulting White Paper. The student received his Masters degree and the thesis remains in the UCLA library.

The HipSaver Company paid Wilson C. Hayes, PhD, a recognized biomechanical engineering expert, to review the graduate student's thesis, the resulting White Paper, and the Posey advertising drawn from the White Paper. Dr. Hayes reported to Hipsaver that the research was not reliable and cannot sustain any of the claims in the White Paper or the resulting Posey advertising with reasonable certainty. Dr. Hayes did not submit any testing results to substantiate his report either to Posey or Hipsaver (as far as I know) based on his criticism of the UCLA testing.

1/17/2006

Page 2 of 2

The HipSaver Company sued the Posey Company. As part of the settlement, Posey agreed to post the Special Announcment on our web site (a link is located on our opening page) and include it with our next catalog mailing. We reached this settlement simply because it was cheaper to settle than pay our expert to fight with their expert in court. I would rather spend our money marketing our excellent products.

CONFIDENTIAL

1/17/2006

Exhibit 13

Case 1:05-cv-10917-PBS Document 183-14 Filed 01/08/2007 Page 2 of 2

Ed Arpawong

From:

Mike Keefe

Sent:

Wednesday, March 23, 2005 3:33 PM

To: Cc: Ed Arpawong Charles Kline

Subject:

Wash Tests

Ed,

I need some special wash tests done before we can make any legal claims against Hipsaver.

We need to have a wash test completed by an outside creditable body that can substantiate our claims that our standard EAR foam can withstand temperatures of 120 degrees and that our Poron foam can withstand temperatures of 180 degrees as we advertise on the label.

We have not had much luck with Angelica and I'm not sure their seal of approval would be worth that all that much. I suggest you contact US Testing and see what they say.

Keep me updated on how you are proceeding with this project because Ernie needs the results before he starts picking on Hipsaver.

Thanks, Mike

Exhibit 14

POSEY HIPSTERS HELP PROTECT AGAINST INJURY FROM FALLS



It's a long way down for residents at risk of injury from falls. You can greatly reduce that risk with Posey Hipsters. The Hipsters' high energy-absorbing foam pads are positioned precisely over the hip bones, increasing the odds of surviving a fall uninjured. The Hipsters are comfortable and slim enough to be virtually undetectable under clothing. By offering increased protection, Hipsters relieve residents' anxiety about falling and enhance their quality of life.

- High impact-absorbing viscoelastic pads protect hip bones against injury from falls
- Soft, comfortable pads improve compliance versus hard-shelled products
- Washable to CDC standards for soiled linen without removing the pads
- 100% latex-free
- Five sizes for correct fit
- Discreet, low-profile pads are virtually undetectable under clothing

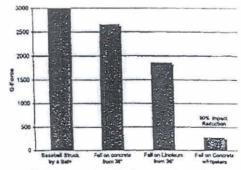


Low Profile -All styles fit discreetly under men's and women's clothing.



Posey Hipsters Proven Effective in Laboratory Test

An independent laboratory study was conducted to determine the most effective impact absorbing material. A test was created that would simulate a fall causing direct impact to the greater trochanter. In this study, a weight was released in a guided drop to simulate a 120 lb. subject falling from a height of 36", or the estimated height of the hip above the floor for a typical nursing home resident. The baseline measurement of impact force was determined to be a fall directly onto concrete. The G-Force of a fall under this scenario was 2,660G's and, for purposes of comparison, is just slightly less impact force than that of a baseball being struck by a bat. In this extreme test, the low profile Posey Hipster reduced the impact force on average by 90% and showed excellent impact energy absorption.



Testing was conducted by Garwood Laboratories. Data on file at J.T. Posey Company "Source: www.madsci.org

Special offer: 30-day no-risk free trial. Test the Posey Hipsters for yourself with no obligation to buy.

Document 156

Filed 12/11/2006

Clinical References Supporting the Use of Hip Protectors

E this attorn

External Hip Protectors to Prevent Osteoporotic Hip Fractures

A. Ekman, H. Mailman, K. Michaelsson, S. Launghall The Lancet, volume 350, August 23, 1997

study Objectives

Eleman and colleagues conducted a controlled study on the use of his projection to prevent hip fractures. One expectation was to cultur confirm or disprove the 1993 reported findings of LB. Lamitteen and collectures in "Effect of external key protectives on his versures.

Results

The use of hip protocoles to preventative treatment for hip fractures was validated. "Our study confirms a reduced no. 1.1

hip fractures of the same magnitude as the previous report."

Recommendations. "With improved compliance external lap protectors should be an effective prophylactic against hip fractures."

Prevention Of Hip Fracture in Elderly People

Di-Paraman

Peldes Kannus, M.D. Ph.D., et al. The New England Journal of Medicine, Vol. 343, No. 21, November 21, 2000

anah Obsertives

The purpose of this study was "to determine whether an external hip protector would be effective in preventing by

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Poults

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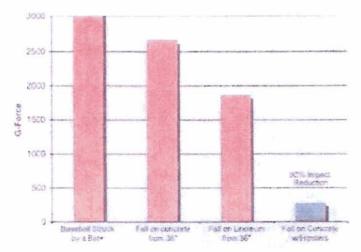
Re-ommendations.

"We conclude that the risk of high fractures can be reduced in final elderly adults through the use of an anatomical." designed external hip protector. Only 41 persons need to use the hip protector for one year (or 8 persons, for five

years) in order for one fracture to be prevented.

Posey Hipsters Proven Effective in Laboratory Test

An independent laboratory study was conducted to determine the most effective impact absorbing material as of July NVI. A seat was created that would simulate a fall-causing direct impact to the greater mechanism. In this study, a worger. a to interest in a guided drop to stimulate a 120th subject failing from a height of 36", or the estimated height of the high a year the floor for a typical nursing home resident. The baseline measurement of impact force was determined to be a fall directly onto concrete. The G-Perce of a fall under this scenario was 2,000G's and, for purposes of comparison. Is such abgirdly less impact horse than that of a baseball being struck by a bar. In this experie test, the low profile Poss-Hirtery reduced the impact force by 90% and showed excellent impact energy absorption.



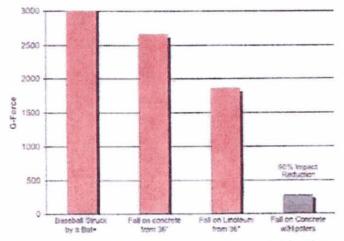
PC 3009

Twiting was conducted by Garwood Laboratories, July 25871, Cate, on file at J.T. Posey Company Country www.madadcorg

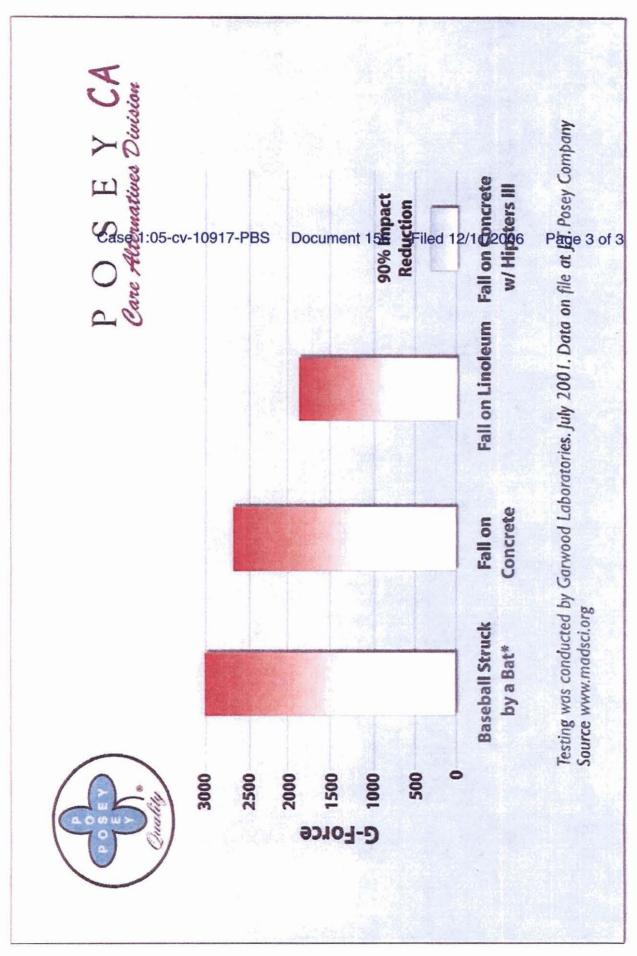
Case 1:05-cv-10917-PBS Document 183-15 Filed 01/08/2007 Page 4 of 7 Case 1:05-cv-10917-PBS Document 156 Filed 12/11/2006 Page 2 of 3

Posey Hipsters Proven Effective in Laboratory Test

An independent laboratory study was conducted to determine the most effective impact absorbing material as of July 2001. A test was created that would simulate a fall causing direct impact to the greater trochanter. In this study, a weight was released in a guided drop to simulate a 120th subject falling from a height of 36°, or the estimated height of the hip above the floor for a typical nursing home resident. The baseline measurement of impact force was determined to be a fall directly onto concrete. The G-Force or a fall under this scenario was 2,660G's and, for purposes of comparison, is just slightly less impact force than that of a baseball being struck by a bat. In this extreme test, the low profile Poscy Hipster reduced the impact force by 90% and showed excellent impact energy absorption.



Testing was conducted by Garwood Laporatones, July 2001. Date on file at J.T. Posey Company. *Source: www.madsc.org



"In an independent laboratory test designed to simulate a fall causing direct impact to the greater trochanter, the Posey Hipster III reduced the impact force by 90%, the best results of any hip protector available."

Case 1:05-cv-10917-PBS Document 156 Filed 12/11/2006 Page 2 of 6

From:

Jeffrey Yates

Sent:

Friday, July 27, 2001 5:30 PM

To:

'Robert Weaver2@med.va.gov'; Gary Platzman

Cc: Subject: Dorene. Opava-Rutter@med.va.gov; Vicky Walters; Ernie Posey; 'jim.mcfall@med.va.gov'

Impact Data regarding Posey Hipsters



HipsterIII VA.doc

Greetings,

Thank you for your message Bob.

Attached to this email is an outline of the impact tests that were recently completed on the New Posey Hipster III product. The New Posey Hipster III absorbs 90% of the impact force of a fall (27% better performance than the current Hipster product).

Manufacturing will begin in a few weeks and I expect we will be in-stock and ready to ship near the end of August.

Vicky and I would like to meet with you early next week to review this study, present the falls research papers we have collected and most importantly, discuss the correlation of the data from the 1994 and 1999 Finnish and studies to the laboratory tests completed on our product this week through an independent testing facility.

If you are in agreement with the test results, Vicky and I would like to work with you on test protocols for a clinical trial on this product and any other products of interest. As Gary and I mentioned during our visit, Posey will provide a reasonable quantity of the Hipster III for clinical trials at NO COST. This is how confident we are that the new Posey Hipster III is the best energy absorbing external hip protector on the market.

I left voicemails for Dr. Rutter and Bob Weaver today (7/27) and will follow-up with another call on Monday to confirm receipt of this email.

I hope you have/had a great weekend.

Jeffrey Yates Director of Marketing J.T. Posey Company 5635 Peck Road Arcadia, CA 91006 (626) 443-3143 x102 (626) 443-5064 - Fax jyates@posey.com

Document 156 Filed 12/11/2006 Page 3 of 6





Posey Company

5635 Peck Road Arcadia, CA 91006-0020 USA Web: www.posev.com

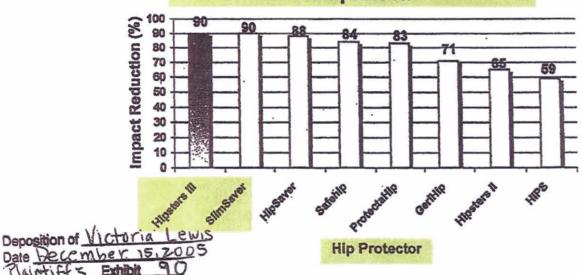
Victoria Walters Product Manager Tel: (626) 443-3143 Ext. 181 Fax: (626) 443-5064 Email: vwalters@posey.com

Posey Impact Test Results July 26, 2001

The graph below depicts the level of impact reduction from different commercially available hip protector products sold in the US when tested according to the following protocol.

- 1. Tests were conducted using a guided drop tower
 - missile weight = 72.5lbs
 - contact surface = 6 inches in diameter
 - drop height 28.5 inches
- 1. Three drops per specimen
- 2. Three-minute recovery time between drops
- 3. Ali measurements were recorded in G-Force
- 4. A baseline of 2,660G was used to measure impact absorption. We estimate that 2,660G's is the approximate impact force to the area of the greater trochanter for a 120lb person falling from a height of 36°.

Hip Protector Impact Reduction Rate Comparison



For Indentification Denise Herit, CSR 12983

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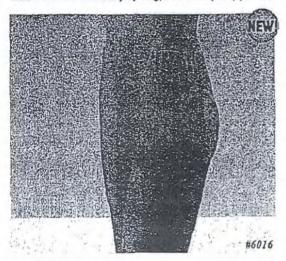
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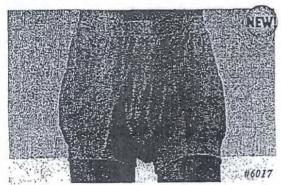


FALL PREVENTION

POSEY HIPSTER: M

Indications: Patients at risk for falling; those at risk for hip fracture.





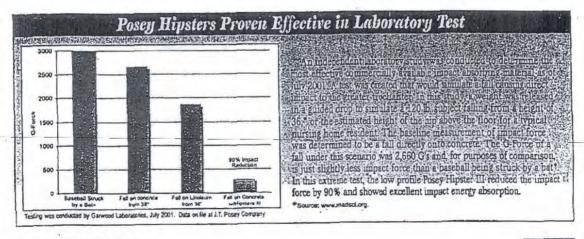
Several studies have documented the efficacy of external hip protectors in preventing hip fractures. The Posey Hipster III features impact absorbing pads over the critical fracture area to help minimize impact assorbing pans over the critical fracture area to help minimize potential damage, including hip fractures that can occur from a fall. The brief is made from comfortable poly-cotton-Lycra® with a low-profile pad positioned over each hip. These low profile pads are sewn into a slim litting brief allowing the Hipster III to be discreetly worn under clothing. The one-piece design allows for easy home or institutional laundering.

Hipster III is available in two styles; standard unisex and incontinent models. The standard unisex brief easily slips on over undergarments or can be worn as underwear. The incontinent brief features a snap front for easier application over adult diapers. The Hipster III fits comfortably around the patient's waist and features a latex-free elastic waistband. 47% polyester, 47% cotton, 6% Lycra. Latex-free.

CAT :		STYLE
6016	(Replaces Poses	s III Standard Brief
6017	Hipsters	
SIZE	WAIST SIZE	HIP SIZE
S	28-30"	35-37"
M	32-34"	33-41"
L	36-38"	43-45"
XL	40-42"	47-49"
XXL	44-46"	51-53"



Low Profile - Both styles fit discreetly under clothing.



1-800-44-POSEY 800-767-3933 fax

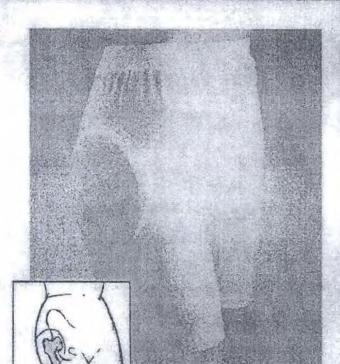
Document 156 Filed 12/11/2006





Posey Hipsters

A better way to protect your patients





- · Soft foam pads help minimize potential damage that can occur from a fall.
- · Low profile, 1/2" thick pads allow the Hipster to be virtually undetectable under clothing.
- · Discreet low-profile pads with soft foam help improve patient compliance.
- NO ASSEMBLY REQUIRED Completely launderable according to CDC standards for soiled linen WITHOUT removing the pads
- 100% Latex Free
- · Incontinent brief features a snap front for easier application over adult dispers. Muy also be worn as a male fly model.
- · Available in five sizes to ensure proper fit.



#6017 Incontinent Brief



Posey Hipsters can be worn discreetly under clothing.

Sixing Chart		
Size	Walst Measurement	Hip Measurement
5	28" - 30"	35* - 37*
M	32" - 34"	39" - 41"
L	36"- 38"	43" - 45"
XL	40*- 42*	47" - 49"
XXI	44" - 48"	51 - 53*

POSEYCA

Care Alternatives Division

For more information or to place an order, contact your Posey District Manager or call 1-800-44-POSEY

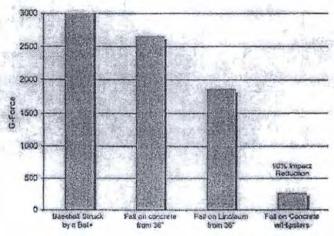
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Page 6 of 6 ...

Posey Hipsters Proven Effective in Laboratory Test

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Testing was conducted by Garwood Laboratories, July 2001. Data on file at J.T. Posay Company

Clinical References Supporting the Use of Hip Protectors

Tale: Author: Publication: External Hip Protectors to Prevent Osteoporotic Hip Fractures A. Ekman, H. Mallmin, K. Michaelsson, S. Ljunghall The Lancet, volume 350, August 23, 1997

PC 3007

Study Objectives:

Ekonan and colleagues conducted a controlled study on the use of hip protection to prevent hip fractures. One expectation was to either confirm or disprove the Lauritzen and colleagues 1993 reported findings.

Results:

The use of hip protectors as preventative treatment for hip fractures was validated. "Our study confirms a reduced

risk for hip fractures of the same magnitude as the previous report."

Recommendations: "With improved complement extensishing processing should be an elicuse prophylactic actions the majorites."

Tule: Author: Prevention Of Hip Fracture in Elderly People Pekka Kannus, M.D., Ph.D., et al.

Publication:

The New England Journal of Medicine, Vol. 343, No. 21, November 21, 2000

Study Objectives:

The purpose of this study was "to determine whether an external hip protector would be effective in preventing hip fractures among elderly adults." The study population was comprised of elderly adults from 22 community based health-care centers in Finland; a treatment group of 653 and a control group of 1,148 participants.

Recuire:

The degree of compliance with the hip protector was 48 ± 29%. The hip protector group suffered 13 hip fractures, 9 of which occurred while not wearing the hip protector, compared to 67 hip fractures in the control group.

Recommendations: "We conclude that the risk of hip fractures can be reduced in frail elderly adults through the use of an anatomically designed external hip protector. Only \$10 persons have because the hippersores for one-year for bijersons for the

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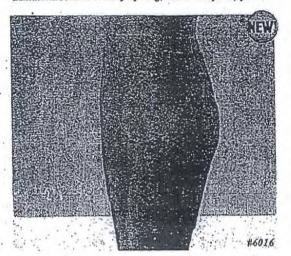
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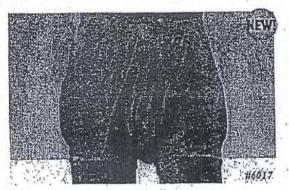


FALL PREVENTION

Posey Hipster III

Indications: Patients at risk for falling; those at risk for hip fracture.





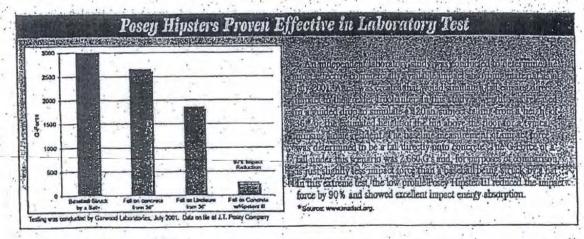
Several studies have documented the efficacy of external hip protectors in preventing hip fractures. The Posey Hipster III features impact absorbing pads over the critical fracture area to help minimize potential damage, including hip fractures that can occur from a fall. The brief is made from comfortable poly-cotton-Lycra® with a lowprofile pad positioned over each hip. These low profile pads are sewn into a slim fitting brief allowing the Hipster III to be discreetly worn under clothing. The one-piece design allows for easy home or institutional laundering.

Hipster III is available in two styles; standard unisex and incontinent models. The standard unisex brief easily slips on over undergarments or can be worn as underwear. The incontinent brief features a snap front for easier application over adult dispers. The Hipster III fits comfortably around the patient's waist and features a latex-free elastic waistband. 47% polyester, 47% cotton, 6% Lycra. Latex-free.

CAT		STILL
6016	(Replaces Poses Hipsters	s III Standard Brief 9 86010 unisez Hipster brief) III Incontinent Brief 011 Incontinent Hipster II brief)
SIZE	WAIST SIZE	HIP SIZE 1
S M L XL XXL	28-30" 32-34" 36-38" 40-42" 44-46"	35-37" 39-41" 41-45" 47-49" 51-53"



Low Profile - Both styles fit discreetly under clothing.



POSEYCA 2002 Fastraint Alternatives



PATIENT SAFETY DIVISION

Document 156

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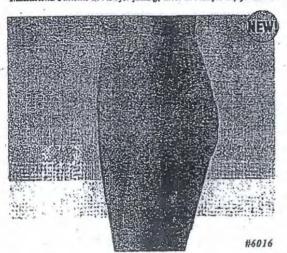
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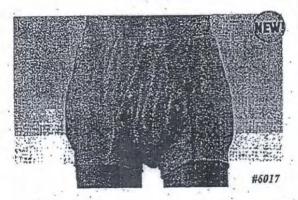


FALL PREVENTION

POSEY HIPSTER III

Indications: Patients at risk for falling; those at risk for hip fracture.





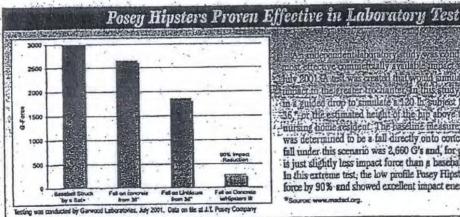
Several studies have documented the efficacy of external hip protectors in preventing hip fractures. The Posey Hipster III features impact absorbing pads over the critical fracture area to belp minimize potential damage, including hip fractures that can occur from a fall. The brief is made from comfortable poly-cotton-lycra* with a low-profile pad positioned over each hip. These low profile pads are sewn into a slim fitting brief allowing the Hipster III to be discreetly worn under clothing. The one-piece design allows for easy home or institutional data. tional laundering.

Hipster III is available in two styles; standard unisex and inconti-nent models. The standard unisex brief easily slips on over undergarments or can be worn as underwear. The incontinent brief features a snap front for easier application over adult diapers. The Hipster III fits comfortably around the patient's waist and features a latex-free clastic waistband. 47% polyester, 47% cotton, 6% Lycra. Latex-free.

CAL		STYLE .	
6016 6017	Hipsters III Standard Brief (Replaces Poscy #5010 unisex Hipster brie Hipsters III Incontinent Brief (Replaces Poscy #6011 Incontinent Hipster II		
SIZE	WAIST SIZE	THIR SIZE IN	
XXL XL XL S	28-30" 32-34" 36-38" 40-42" 44-46"	15-37" 39-41" 43-45" 47-49" 51-53"	



Low Profile - Both styles fit discreetly under clothing.



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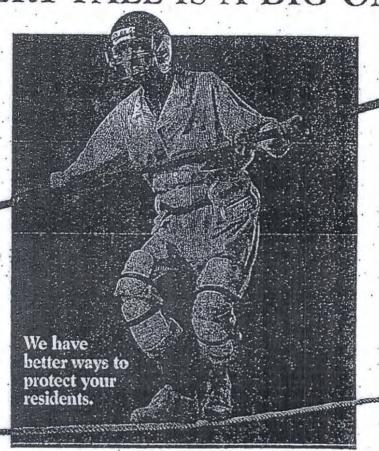
1-800-44-POSEY

800-767-3933 fax

Document 156

Filed 12/11/2006

FOR SOME RESIDENTS, EVERY FALL IS A BIG ONE.



POSEY HIPSTERS

It's a long way down for residents at risk of injury from falls. You can greatly reduce that risk with Posey Hipsters. High energy-absorbing, viscoelastic foam pads built into Hipsters increase the odds of surviving a fall uninjured. They are comfortable and slim enough to be virtually undetectable beneath clothing.

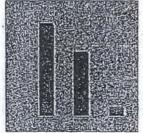
By offering increased protection, Hipsters relieve residents' anxiety about falling and enhance their quality of life.



IMPACT REDUCED BY 90%

An independent laboratory study simulated the fall of a 120-lb object onto concrete from a height of 36". Posey Hipster pads reduced the impact force by 90%.

Data on file at J.T. Posey Company.



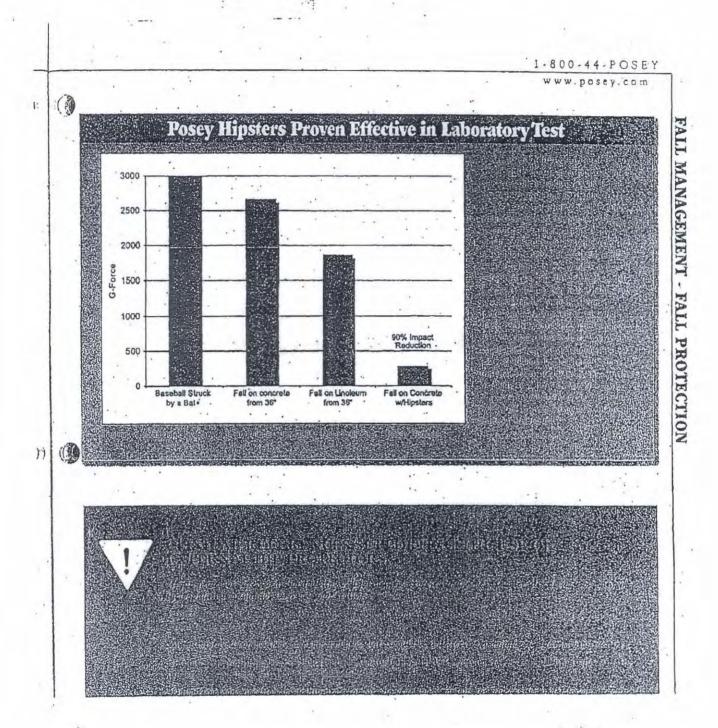
SPECIAL OFFER: 30-day no-obligation free trial.

Test the new Hipster for yourself at no charge. Call or visit our Website today to start your free trial.

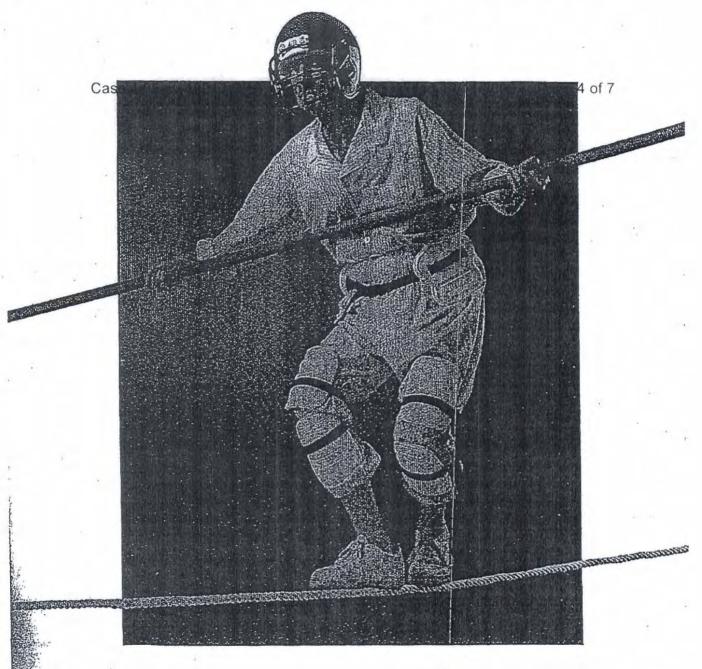
POSEYCA Care Alternatives Division Fall Protection That Fits

J.T. Posey Company, 5635 Peck Road, Arcadia, CA 91006-0020 www.posey.com 1-800-44-POSEY CATLREDS 091702

Case 1:05-cv-10917-PBS Document 156 Filed 12/11/2006 Page 3 of 7

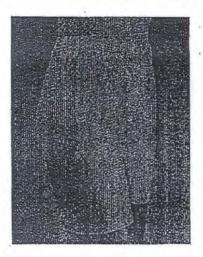


FOR SOME RESIDENTS, EVERY FALL IS A BIG ONE



POSEY CA Care Alternatives Division

POSEY HIPSTERS PROTECT AGAINST INJURY FROM FALLS

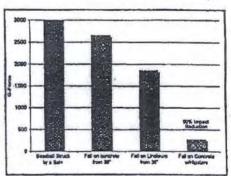


It's a long way down for residents at risk of injury from falls. You can greatly reduce that risk with Posey Hipsters. The Hipsters' high energy-absorbing foam pads are positioned precisely over the hip bones, increasing the odds of surviving a fall uninjured. The Hipsters are comfortable and slim enough to be virtually undetectable under clothing. By offering increased protection, Hipsters relieve residents' anxiety about falling and enhance their quality of life.

- High impact-absorbing viscoelastic pads protect hip bones against injury from falls
- Soft, comfortable pads improve compliance versus hard-shelled products
- Washable to CDC standards for soiled linen without removing the pads
- 100% latex-free
- Five sizes for correct fit
- Discreet, low-profile pads are virtually undetectable under clothing



Low Profile -All styles fit discreetly under men's and women's clothing. PROVEN IMPACT REDUCTION
In an independent laboratory, simulating a fall from a height of 36 inches, the Hipsters reduced the impact force by over 90%.

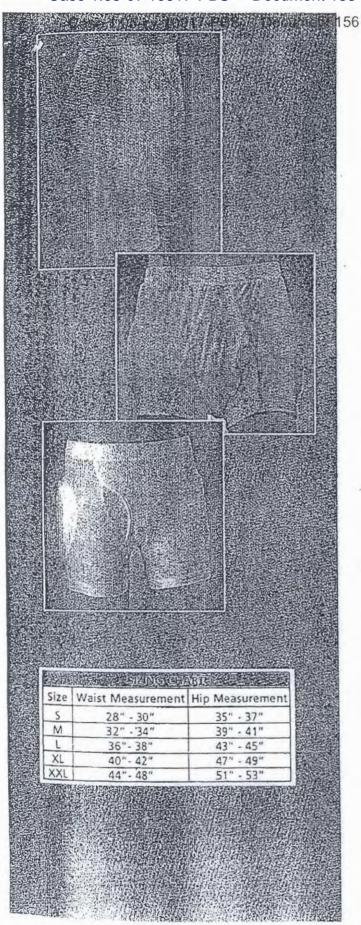


Testing was conducted by Garwood Laboratories, July 2001. Data on file at J.T. Posey Company

POSEY CA Care Alternatives Division

PC 1807

Special offer 30 day no risk free trial.



Filed 12/11/2006 Page 6 of 7
#6016 HIPSTERS STANDARD
BRIEF

- Easily fits on over undergarments, or can be worn as underwear.
- Unisex sizing

#6017 INCONTINENT BRIEF

- Snap front for easier application over diaper
- Unisex sizing

#6018 MALE FLY BRIEF

- Easily fits on over undergarments, or can be worn as underwear
- Fly front for improved compliance in male residents



Case 1:05 cv 10917-PBS Document 156 Filed 12/11/2006 Page 7 of 7 Clinical References Supporting the Use of Hip Protectors

Title: Author: Publication: External Hip Rrotectors to Prevent Osteoporotic Hip Fractures

A. Ekman, H. Mallmin, K. Michaëlsson, S. Ljunghall The Lancet, volume 350, August 23, 1997

Study Objectives:

Ekman and colleagues conducted a controlled study on the use of hip protection to prevent hip fractures. One expectation was to either confirm or disprove the 1993 reported findings of J.B. Lauritzen and colleagues in "Effect of exter-

nal hip protectors on hip fractures."

Results:

The use of hip protectors as preventative treatment for hip fractures was validated. "Our study confirms a reduced risk for hip fractures of the same magnitude as the previous report."

Recommendations:

With approved adoptions and one in protectors should be applied on a month facility against the

Title:

Prevention Of Hip Fracture in Elderly People

Author:

Pekka Kannus, M.D., Ph.D., et al

Publication:

The New England Journal of Medicine, Vol. 343, No. 21, November 21, 2000

Study Objectives:

The purpose of this study was "to determine whether an external hip protector would be effective in preventing hip fractures among elderly adults." The study population was comprised of elderly adults from 22 community based health-care centers in Finland; a treatment group of 653 and a control group of 1,148 participants.

Results:

The degree of compliance with the hip protector was $48 \pm 29\%$. The hip protector group suffered 13 hip fractures, 9 of which occurred while not wearing the hip protector, compared to 67 hip fractures in the control group.

Recommendations:

"We conclude that the risk of hip fractures can be reduced in frail elderly adults through the use of an anatomically designed external hip protector.

Please detach and fax to 1-800-767-3933, or call us at 1-800-44-POSEY to start your trial

yes!

I want to take advantage of your 30-day trial offer. Please have a representative call me to discuss Posey Hipsters.



Name		=
Title		4
Institution	93	
Address		
City	State	Zip
Telephone ()	Best time to	call am pm

Fax or mail to:



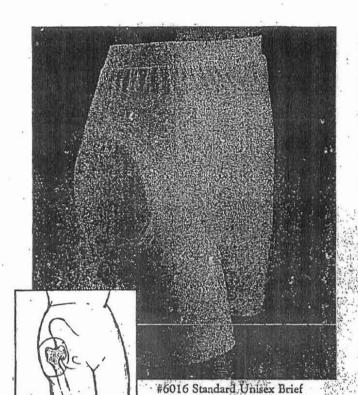
J.T. Posey Company Attn: Marketing Dept. 5635 Peck Road Arcadia, CA 91006-0020 Fax 800-767-3933

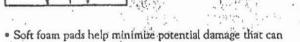
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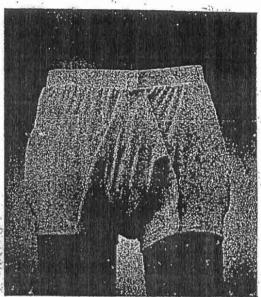




- Low profile, '/i" thick pads allow the Hipster to be virtually undetectable under clothing.
- Discreet low-profile pads with soft foam help improve patient compliance.
- NO ASSEMBLY REQUIRED Completely launderable according to CDC standards for soiled linen WITHOUT removing the pads.
- 100% Latex Free

occur from a fall.

- Incontinent brief features a snap front for easier application over adult diapers. May also be worn as a male fly model.
- · Available in five sizes to ensure proper fit.



#6017 Incontinent Brief



Posey Hipsters can be worn discreetly under clothing.

Size	Waist Measurement	Hip Measurement
S	28" - 30" .	35" - 37"
M	32" - 34"	39" - 41"
L	36"- 38"	43" - 45"
XI.	40"- 42" -	47" - 49"
XXL	44"- 48"	51* - 53*.

See reverse

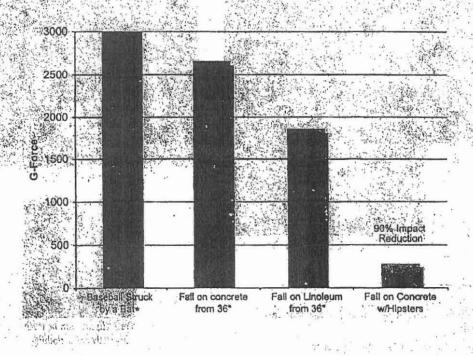
Document 156

Filed 12/11/2006

Page 3 of 5

Posey Hipsters Proven Effective in Laboratory Test

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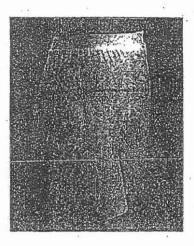


For more information or to place an order, contact your Posey District Manager or call 1-800-44-POSEY

Document 156

Filed 12/11/2006 Page 4 of 5

POSEY HIPSTERS PROTECT AGAINST INJU FROM FALLS



It's a long way down for residents at risk of injury from falls. You can greatly reduce that risk with Posey Hipsters. The Hipsters' high energy-absorbing foam pads are positioned precisely over the hip bones, increasing the odds of surviving a fall uninjured. The Hipsters are comfortable and slim enough to be virtually undetectable under clothing. By offering increased protection, Hipsters relieve residents' anxiety about falling and enhance their quality of life.

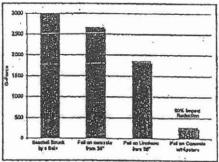
- High impact-absorbing viscoelastic pads protect hip bones against injury from falls
- Soft, comfortable pads improve compliance versus hard-shelled products
- Washable to CDC standards for soiled linen without removing the pads
- \$ 100% latex-free
- Five sizes for correct fit .
- B Discreet, low-profile pads are virtually undetectable under clothing



Low Profile . All styles fit discreetly under men's and women's clothing.

PROVEN IMPACT REDUCTION

In an independent laboratory, simulating a fall from a height of 36 inches, the Hipsters reduced the impact force by over 90%.



Testing was conducted by Garwood Laboratories, July 2001. Data on file at J.T. Posey Company

POSEY Care Alternatives Division

PC 0408

Special offer: 30-day no-risk free trial. Test the Posey Hipsters for yourself with no obligation to buy.

Document 156

Filed 12/11/2006

Page 5 of 5

Clinical References Supporting the Use of Hip Protectors

Title: Author: Publication: External Hip Protectors to Prevent Osteoporotic Hip Fractures

A. Ekman, H. Mallmin, K. Michaëlsson, S. Ljunghall The Lancet, volume 350, August 23, 1997

Study Objectives:

Ekman and colleagues conducted a controlled study on the use of hip protection to prevent hip fractures. One expectation was to either confirm or disprove the 1993 reported findings of J.B. Lauritzen and colleagues in "Effect of exter-

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The use of hip protectors as preventative treatment for hip fractures was validated. "Our study confirms a

reduced risk for hip fractures of the same magnitude as the previous report."

Recommendations:

"With improved compliance, external hip protectors should be an effective prophylactic against hip

fractures."

Title:

Prevention Of Hip Fracture in Elderly People

Author:

Pekka Kannus, M.D., Ph.D., et al

Publication:

The New England Journal of Medicine, Vol. 343, No. 21, November 21, 2000

Study Objectives:

The purpose of this study was "to determine whether an external hip protector would be effective in preventing hip fractures among elderly adults." The study population was comprised of elderly adults from 22 community based health-care centers in Finland; a treatment group of 653 and a control group of 1,148 participants.

Results:

The degree of compliance with the hip protector was 48 ± 29%. The hip protector group suffered 13 hip fractures, 9 of which occurred while not wearing the hip protector, compared to 67 hip fractures in the control group.

Recommendations: "We conclude that the risk of hip fractures can be reduced in frail elderly adults through the use of an anatomically designed external hip protector. Only 41 persons need to use the hip protector for one year (or 8 persons, for five years) in order for one fracture to be prevented."

Please detach and fax to 1-800-767-3933, or call us at 1-800-44-POSEY to start your trial

I want to take advantage of your 30-day trial offer. Please have a representative call me to discuss Posey Hipsters.



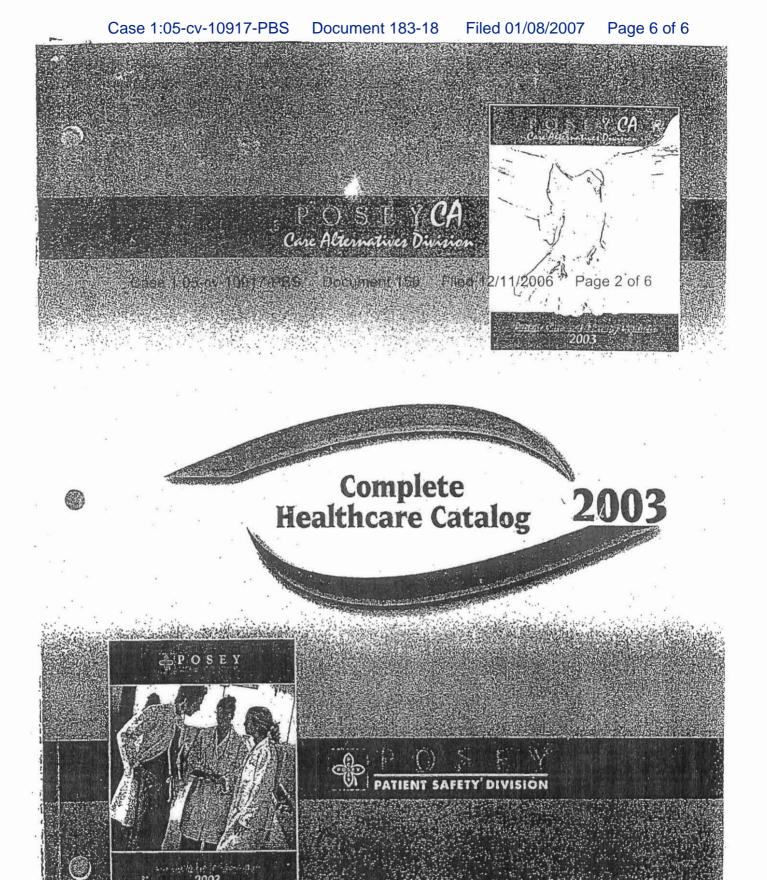
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Fax or mail to:



J.T. Posey Company Attn: Marketing Dept. 5635 Peck Road Arcadia, CA 91006-0020 Fax 800-767-3933

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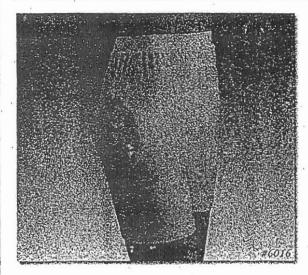
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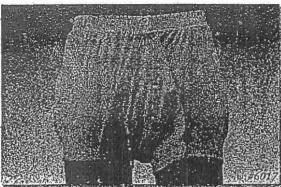
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Page 3 of 6



POSINGHILISHERS







Studies have documented the efficacy of external hip protectors in preventing hip fractures. Posey Hipsters feature impact absorbing pads over the critical hip fracture area to minimize potential damage, including hip fractures, that can occur from a fail. The brief is made from comfortable poly-cotton-tycra with a low profile pad positioned over each hip. These low profile pads are sewn into a slim fitting brief allowing the Hipsters to be discreedy worn under clothing. The one-piece design allows for easy home or institutional laundering.

Hipsters are available in three styles; standard unisex brief, male fly brief, and incontinent models. The standard unisex brief and male fly models easily slip on over undergarments or can be worn as underwear. The incontinent brief features a snap front for easier application over adult diapers. The Hipsters fit comfortably around the patient's walst and feature a latex-free elastic waistband. 47% polyester, 47% cotton, 6% Lycra: Latex-free.

CAT.#	STYLE	
6016	Hipsters Standard Brief	
6017	Hipsters Incontinent Brief	
6018	Hipsters Male Fly Brief	

T.Y	SIZE	100	WAIST SIZE	HIP SIZE	100	l for	
	5		28-30"	35-37*		*	
	84	(4):00	32-34*	39-41"			
	L		36-38"	43-45*			
	XL		40-42	 47-49"			
	XXI.	*-	44-46"	51-53			



Low Profile -Both styles fit discreetly under clothing

PC 1034

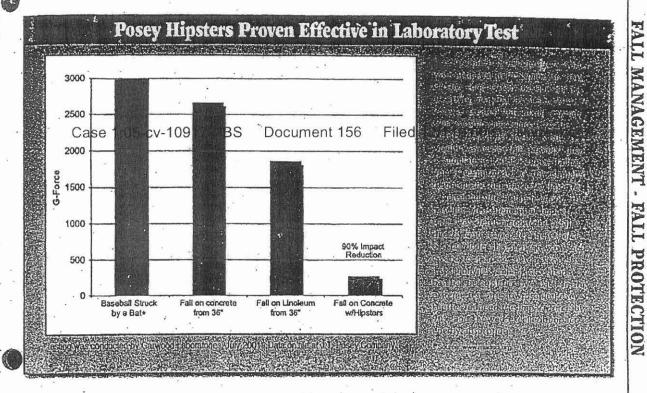
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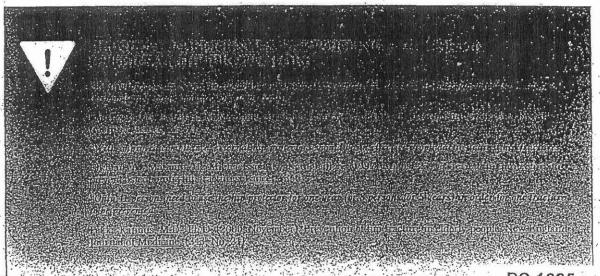
FALL MANAGEMENT

1

1-800-44-POSEY

www.posey.com





PC 1035

FALL FACTS:

In 1996 older Americans suffered htp://ractures at a cost in excess of \$10 billion.

(Saures George & Faile, Cal MC bills in the Elderly, American Family Physician, April 2000)

Document 156

Filed 12/11/2006





Posey EZ On Hipsters

In 1996, hospital admissions for hip fractures among people aged 65 and older totaled 340,000 and is expected to exceed 500,000 with a projected annual cost of \$240 billion by the year 2040. Tragically, half of all older adults hospitalized for hip fractures cannot return home or live independently after their injury and about one quarter will die within one year due to the fracture or related complications.2

Several studies have documented the efficacy of external hip protectors in preventing hip fractures. These same studies also point out that patient compliance is a driving factor in product effectiveness. Posey Hipsters feature impact absorbing, soft foam pads over the critical fracture area to help minimize potential damage, including hip fractures that can occur from a fall. The low profile pads allow the Hipsters to be discreetly worn under clothing. These soft pads offer greater comfort when compared to hard shell style hip protectors. Patient comfort, coupled with the low profile design, helps increase patient compliance.

The EZ On Hipsters are applied around the waist and lower thigh using the hook-and-loop attachments, and allow the patients to wear their own undergarments. The mesh material is water permeable, allowing the EZ On Hipsters to be worn during bathing.

EZ On Hipsters feature removable pads. Although the pads are removable, the Hipsters can be laundered with the pads in place. Removing the pads prior to laundering will help prolong the life of the product.

While no product can provide complete protection from hip fractures, Posey Hipsters will help to minimize the potential for damage that can occur from a fall.

#6019 EZ On Hipsters

#6008 Replacement Pads, 1 pair

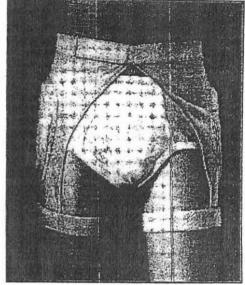
Application Instructions

- Unfasten the hook and loop at the waist and thighs.
 Wrap the garment around your waist. The labels should be oriented towards the back and on the inside of the waistband.
- 3. Fasten the hook and loop at the front of your waist. The waistband should be securely fastened to allow minimal shifting of the garment but should not feel tight or restrictive.
- 4. Pull the left panel taut over the left hip and thigh. The pad should be positioned directly over the hip joint.
- Secure around the lower thigh using the hook and loop attachment. The elastic band should be tight enough to prevent the pad from sliding out of place without restricting circulation.
- 6. Repeat steps 4 and 5 on right side.

Laundering Instructions

Posey Hipsters may be washed according to CDC standards (see symbols below). Using the lower temperature washing and drying cycle for non-contaminated linen will prolong product life.

- If hook and loop does not adhere, it is most likely due to a collection of lint. Clean hook by brushing with a stiff brush.
- If pads are removed, wipe clean with mild, liquid disinfectant before replacing in the pants.



#6019

Size	Waist Measurement	Hip Measurement
S	28" - 30"	35" - 37"
M	32" - 34"	39* - 41*
L	36"- 38"	43* - 45*
XL	40"- 42"	47" - 49"
XXL	44"- 48"	51* - 53*

AWARNING

Due to the random possibilities of fall characteristics, the Posey Company makes no guarantee, express or implied, that the user is protected from hip trauma. The skin under the pants should be assessed regularly and Hipsters should be changed and washed after each incontinent episode to prevent skin breakdown.

AWARNING

- · Posey Hipsters contain foam pads that are sealed in a pouch to protect the foam.
- If the pouch is cut or the seal is broken in laundering, moisture will enter the pouch and compromise the impact absorption quality of the foam.
- · Test pouch and foam integrity by squeezing the pad in one fist, forcing the air to one end, resulting in an air bubble.
- · If you hear or feel air or liquid escaping, or the foam feels soft and spongy, the pouch is damaged.

 Remove the damaged pouch and replace with a
- new one.

1 Centers for Disease Control and Prevention. 3 Aug 2001, www.cdc.gov. 2 Rubenstein, Laurence, M.D., M.P.H. (2000) Hip Protectors - A Breakthrough in Fracture Prevention. The New England Journal of Medicin J.T. Posey Company 5635 Peck Road - Arcadia, CA 91006-0020 USA - Tel: 800-447-6739 or 626-443-3143 - Fax: 800-757-3933 or 626-443-5014 - www.posey.com EU AUTH. PERSON: (MDO 93/42/EEC) MDSS GmbH, Burckherdtstr. 1, D-30163, Hannover, Germany

ON CONTAINER

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Document 156

Filed 12/11/2006

Page 6 of 6

Clinical References Supporting the Use of Hip Protectors

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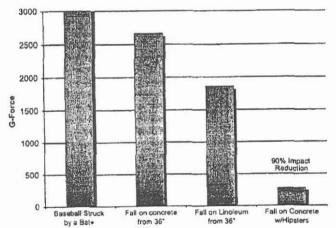
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Posey Hipsters Proven Effective in Laboratory Test

An independent laboratory study was conducted to determine the most effective impact absorbing material as of July 2001. A test was created that would simulate a fall causing direct impact to the greater trochanter. In this study, a weight was released in a guided drop to simulate a 120lb subject falling from a height of 36°, or the estimated height of the hip above the floor for a typical nursing home resident. The baseline measurement of impact force was determined to be a fall directly onto concrete. The G-Force of a fall under this scenario was 2,660G's and, for purposes of comparison, is just slightly less impact force than that of a baseball being struck by a bat. In this extreme test, the low profile Posey Hipster reduced the impact force by 90% and showed excellent impact energy absorption.



Testing was conducted by Garwood Laboratories, July 2001, Data on file at J.T. Posey Company

J.T. Posey Company, 5635 Peck Road. Arcadia, CA 91006-0020 . Phone 800-447-6739 . Fax 800-767-3933 . www.posey.com

Case 1:05-cv-10917-PBS Document 156 Filed 12/11/2006



Posey® EZ On Hipsters

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EZ On Hipsters feature removable pads. Although the pads are removable, the Hipsters can be laundered with the pads in place. Removing the pads prior to laundering will help prolong the life of the product.

While no product can provide complete protection from hip fractures; Posey Hipsters will help to minimize the potential for damage that can occur from a fall.

#6019 EZ On Hipsters #6008 Replacement Pads, 1 pair

Application instructions

1. Unfasten the hook and loop at the waist and thighs

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5. Secure around the lower thigh using the hook and loop attachment. The elastic band should be tight enough to prevent the pad from sliding out of place without restricting circulation.

6. Repeat steps 4 and 5 on right side.

Laundering Instructions

For longest garment life wash hot, dry on low and bleach as on container "Studies have shown that a satisfactory reduction microbial contamination can be achieved at water temperatures lower than 160°F if laundry chemicals suitable for low-temperature washing are used at proper concentrations. In the home, normal washing and drying cycles including 'hor' or 'cold' cycles are adequate to ensure patient safety. Instructions of the manufacturiers define machine and the detergent or wash additive should be followed closely." Washing and drying cycles with higher temperatures will shorten garment life.

If hook and loop does not adhere, it is most likely due to a collection of lint. Clean block by brushing with a stiff by significant before replacing in the parts.

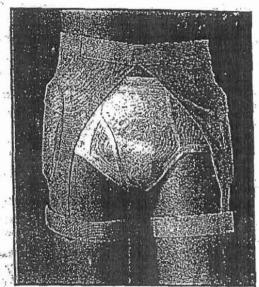
before replacing in the pants











#6019

v .	Sizing Char	t ·
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J.T. Posey Company 5635 Peck Road • Artadia CA 91006-0020 USA • Jet 800-47-6739 or 626-443-3143 • Fax. 800-767-3933 or 626-443-5014 • www.posey.com
EU AUTH PERSON RADO STREET, MOSS Graph, Burdshardstr. 1, D-20163, Harmour, Germany

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Document 156

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Page 3 of 6

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Recommendations:

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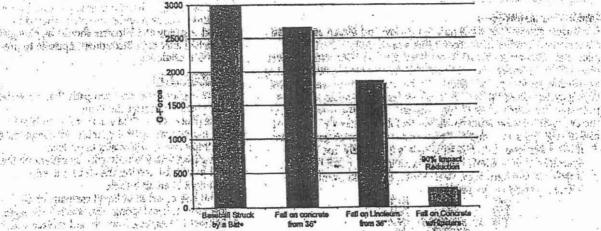
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Posey Hipsters Proven Effective in Laboratory Test

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J.T. Posey Company, 5635 Peck Road, Arcadia, CA 91006-0020 . Phone 800-447-6739 . Fax 800-767-3933 . www.posey.com

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the Posey Hipsters for

self with no obligation to buy.

Special offer 30-day no-risk free trial

Posey engaged Garwood Labonatories to conduct testing to select a combratable and effective impact absorbing material. A rase was created that would simulate a fall causing direct impact to the greater mechanica in this study, a weight was released in a guided shop to simulate a 120 lb, subject falling from a height of 30°, or the estimated height of the hip above the floor for a typical nursing home resident. The

Poscy Hipsters Proven Effective in Laboratory Test



It's a long way down for residents at risk of injury from falls. You can greatly reduce that risk with Posey Hipsters. The Hipsters high energy-absorbing foam pads are

positioned precisely over the hip bones, increasing the odds of surviving a fall uninjured. The Hipsters are comfortable and slim enough to be virtually underectable

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High impact-absorbing viscoelastic pads protect hip bones against injury from falls

85, 100% lates-free without removing the pads Washable to CDX standards for solled linen Soft, comfortable pads improve compliance versus hard-shelled products



B. Discreet, low-profile pads are virtually undetectable under clothing

Five sizes for correct fit























POSEY #6019 EZ-ON BRIEF Reddents can wear their own updergarments.

POSSY #6018 MALE FIY BRIEF

Eatily fits over undergaments, or can be worn as underwear.

Fy front for improved compliance in galac residents. © #6018H Male Fly Brief with high dispability pads.

The Can be worn in the shower.

The Highpads can be removed for ladbidering or replacement.



POSDY #6016 HIPSTERS
STANDARD BRIEF

P. Fasily fits over undergaments, or ca
be worn as underwear.

POSTA #6017 INCONTINENT BRIEF Sing front for easier application over disper. Unisex sizing.

S #6017H Incontinent Brief with high dutability pads.

D Ubgex sizing. #6016H Standard Brief with high digability pads.

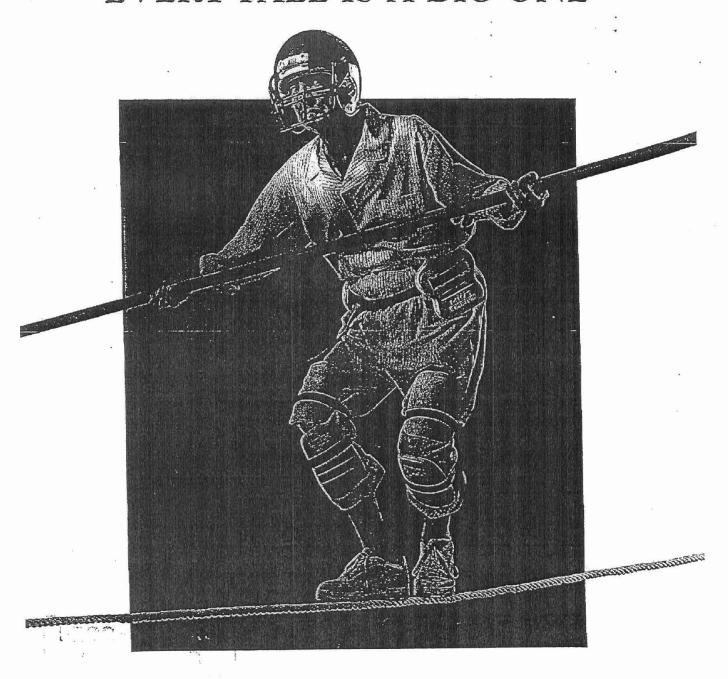


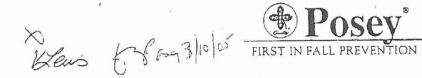


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127	Valst Measuremen
	18"-30" or 71-76gr
_	37 - 34" or 76 - 86cm
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	36-42" or 96-1060
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Case 1:05-cv-10917-PBS Document 156 Filed 12/11/2006 Page 5 of 6

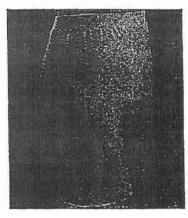
FOR SOME RESIDENTS, EVERY FALL IS A BIG ONE







POSEY HIPSTERS HELP PROTECT AGAINST INJURY FROM FALLS



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- High impact-absorbing viscoelastic pads protect hip bones against injury from falls
- Soft, comfortable pads improve compliance versus hard-shelled products
- Washable to CDC standards for soiled linen without removing the pads
- 100% latex-free
- Five sizes for correct fit
- Discreet, low-profile pads are virtually undetectable under clothing

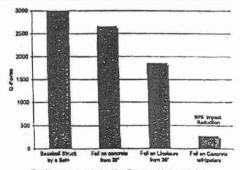


Low Profile -All styles fit discreetly under men's and women's clothing.



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Testing was conducted by Garwood Laboratories.

Data on file at J.T. Posey Company 'Source: www.madsci.org

Special offer: 30-day no-risk free trial.

Test the Posey Hipsters for yourself with no obligation to buy.

#6016H

#6017/#6017H

6018/#6018H

#6019/#6019**H**

Document 156 Filed 12/11/2006

Page 2 of 7

POSEŸ #6016 HIPSTERS STANDARD BRIEF

- Easily fits over undergarments, or can be worn as underwear.
- Unisex sizing.



#6016H Standard Brief with high durability pads.

POSEY #6017 INCONTINENT BRIEF

- Snap front for easier application over diaper. Unisex sizing.
- #6017H Incontinent Brief with high durability pads.

POSEY #6018 MALE FLY BRIEF

- Easily fits over undergarments, or can be worn as underwear.
- Fly front for improved compliance in male residents.



#6018H Male Fly Brief with high durability pads.

POSEY #6019 EZ-ON BRIEF

- Residents can wear their own undergarments.
- Can be worn in the shower.
- Hip pads can be removed for laundering or replacement.
- (131)
- #6019H EZ-ON Brief with high durability pad.

	SIZING CH	ART
Size	Waist Measurement	Hip Measurement
S	28" - 30" or 71 - 76cm	35" - 37" or 88 - 93cm
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L	34"-38" or 86 - 96cm	41" - 45" or 104 - 114cm
XL	38"-42" or 96 - 106cm	45" - 49" or 114 - 124cm
XXL	42"-46" or 106 - 116cm	49" - 53" or 124 - 134cm

Posey High Durability Hipsters contain denser foam than the standard Hipsters. This increased density aids in its ability to withstand higher hot washing and drying cycles.

LAUNDERING INSTRUCTIONS:

Hipsters







High Durability Hipsters WASH HOT

BLEACH AS DIRECTED ON CONTAINER DRY DN HIGH



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Document 156

Filed 12/11/2006

Page 3 of 7

Clinical-References Supporting the Use of Hip Protectors

Title:

External Hip Protectors to Prevent Osteoporotic Hip Fractures

Author: Publication: A. Ekman, H. Mallmin, K. Michaëlsson, S. Ljunghall The Lancet, volume 350, August 23, 1997

Study Objectives:

Ekman and colleagues conducted a controlled study on the use of hip protection to prevent hip fractures. One expectation was to either confirm or disprove the 1993 reported findings of J.B. Lauritzen and colleagues in "Effect of exter-

nal hip protectors on hip fractures."

Results:

The use of hip protectors as preventative treatment for hip fractures was validated. "Our study confirms a

reduced risk for hip fractures of the same magnitude as the previous report."

Recommendations:

"With improved compliance, external hip protectors should be an effective prophylactic against hip

fractures,

Title:

Prevention Of Hip Fracture in Elderly People

Author

Pekka Kannus, M.D., Ph.D., et al

Publication:

The New England Journal of Medicine, Vol. 343, No. 21, November 21, 2000

Study Objectives:

The purpose of this study was "to determine whether an external hip protector would be effective in preventing hip fractures among elderly adults." The study population was comprised of elderly adults from 22 community based health-care centers in Finland; a treatment group of 653 and a control group of 1,148 participants.

Results:

The degree of compliance with the hip protector was 48 ± 29%. The hip protector group suffered 13 hip fractures, 9 of which occurred while not wearing the hip protector, compared to 67 hip fractures in the control group.

Recommendations: "We conclude that the risk of hip fractures can be reduced in frail elderly adults through the use of an anatomically designed external hip protector. Only 4 spersons need no use the hip protectors for one year (on 8 persons, for rive years) an order for one macture to be prevented.

Posey Hipsters can be washed according to CDC guidelines for soiled linen. Hipsters with high durability pads are designed to withstand laundering in large capacity machines at higher temperature hot (180°) washing and high temperature drying cycles.

Due to the random possibility of falls, the Posey Company makes no guarantee, express or implied, that the user is protected from hip trauma.

Please detach and fax to1-626-443-5014, or call us at 1-800-44-POSEY to start your trial

I want to take advantage of your 30-day trial offer. Please have a representative call me to discuss Posey Hipsters.



Name	1		
Ticle			
Institution			
Address			
City	State	Zip	
Telephone ()	Best time to call	am	pπ

Fax or mail to:



J.T. Posey Company Attn: Marketing Dept. 5635 Peck Road Arcadia, CA 91006-0020 USA Fax 626-443-5014 www.posey.com

PC 1746

M6079 010305

Clinical References Supporting the Use of Hip Protectors

External Hip Protectors to Prevent Osteoporotic Hip Fractures
A. Ekman, H. Mallmin, K. Michaelsson, S. Ljunghall
The Lancet, volume 350, August 23, 1997

FOR SOME RES EVERY FALL IS A

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Prine detach and far to 1-436-443-1014, or call as et 1-400-44-POSIV to etan your trial

SHEET STATE

Fex or mail to:

FIRST IN FALL PREVENT

of 7

PC 0400

I want to take advancage of your 30-day trial offer.

Please have a representative call me to discuss Posey Hipsters.

Arra: Markeding Dept. 5633 Peck Raud Arcadia, CA 91006-0020 USA Fax 626-443-5014

POSEY #6016 HIPSTERS STANDARD BRIEF

6

E. Easily fits over undergarments, or can be worn as underwear.

取 Unisex sizing. 取 #6016H Standard Brief with high durability pads.

POSEY #6017 INCONTINENT BRIEF

Snap front for easier application over diaper. Unitex sizing. \$\$ \$607H Incontinent Brief with high durability pads.

S Easily fits over undergarments, or can be worn as underwear. Fly front for Improved compliance in male residents.

\$\$ #6018H Male Fly Brief with high durability pads.

POSEY #6019 EZ-ON BRIEF Residents can wear their own The shown in the shower.

The pads can be removed for all alundering or replacement.

The #6019H E2-ON Brief with high durability pad.



Posey High Dumbilly Hipsters contain denser foam than the standard Hipsters. This focuessed density sids in its ebility to withstand higher hot weathing and dryfug cycles.

AUNDERING INSTRUCTIONS:



O

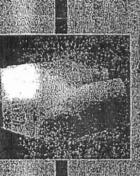




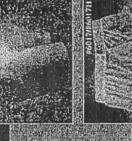


J T Posey Company Arcadia, CA 91006 USA Tel: 800-447-6739

POSEY #6018 MALE FLY BRIEF undergarments. 1







It's a long way down for residents at risk of injury from falls. You can greatly reduce that risk with Posey Hipsters. The Hipsters high energy-absorbing foam pads are positioned precisely over the hip bones, increesing the odds of surviving a full unitajured. The Hipsters are comfortable and slim enough to be virtually underectable unitajured. The Hipsters are comfortable and slim enough to be virtually underectable under-certainer. Without in the constant anxiety about falling and enhance their quality of life.





E Soft comfortable pads Improve compilance versus hard-shelled products B. Washable to CDC standards for soiled linen

without removing the pads

High impact-absorbing viscoelastic pads protect hip banes against injury from falls





Posey Hipsters Proven Effective in Laboratory Test

Discreet, low-profile pads are virtually underectable under clothing

Five sizes for correct fit Il. 100% latex-free













3

Passy cripaged Garwood Lubranories to conduct testing to select a comfortable and defective impact absorbing material. Select a comfortable and defective impact absorbing material. A test was created that would afmiliate a fell catasting direction are closed in this society as weight was released to a galded drop to stimiture a 120 lb, subject falling from a height of 18°, or the estimated height of the hip show, the Boot fell or a typical numing home resident. The baselite measurement of impact four was determined to be a fell directly more controle. The Chen of a fell under this secretio was 2.660Cs and, for purposes of comparison, its just slightly less impact (mary than for a leaded) laking, such this secretion was 1.660Cs and for the proposes of comparison, its just slightly less impact (more than that of a leaded) laking.

Test the Posey Hipsters for yourself with no obligation to buy. Special offer: 30-day no-risk free trial.

Case 1:05-cv-10917-1788 0000cument 156

Filed 12/11/2006





1

Posey® Hipsters™

Posey Hipsters feature impact absorbing, soft foam pads over the critical fracture area to help minimize potential damage, including hip fractures that can occur from a fall.

Hipsters are available in four styles:

- Standard Unisex Brief easily fits over undergarments, or can be worn as underwear.
- Incontinent Brief features a snap front for easier application over adult diapers.
- Male Fly Brief easily fits over undergarments, or can be worn as underwear.
- EZ-On Brief features a crotchless design that allows patients to wear their own undergarments. The mesh material is water permeable, allowing the EZ On Hipster to be worn during bathing.

All Hipsters are available with original foam padding, or high durability padding designed to withstand laundering in large capacity machines at higher temperature hot washing cycles.

- REF 6016 Hipsters, Standard Brief
- REF 6017 Hipsters, Incontinent Brief
- REF 6018 Hipsters, Male Fly Brief
- REF 6019 Hipsters, EZ On
- REF 6008 Replacement Pads, 1 pair
- REF 6016H Hipsters, High Durability Pads, Standard Brief
- AEF 6017H Hipsters, High Durability Pads, Incontinent Brief
- REF 6018H Hipsters, High Durability Pads, Male Fly Brief
- ALF 6019H Hipsters, High Durability Pads, EZ On
- REF 6008H Replacement High Durability Pads, 1 pair

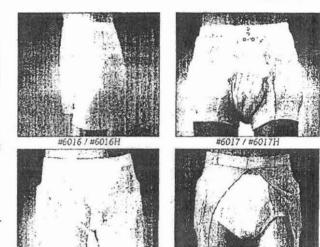
Application Instructions:

Standard, Male Fly and Incontinent Brief Models
With the Posey label in the back, put the Hipsters on as you would a pair of shorts, sliding them gently over the hips. Adjust to assure that the foam pads are properly aligned with and cover the hip joint.

EZ On Model

- 1. Unfasten the hook and loop at the waist and thighs.
- Wrap the garment around your waist. The labels should be at the back and on the inside of the waistband.
- Fasten the hook and loop at the front of your waist. The waistband should be securely fastened to allow minimal shifting of the garment, but should not feel tight or restrictive.
- Pull the left panel taut over the left hip and thigh. The pad should be positioned directly over the hip joint.
- Secure the leg band around the lower thigh using the hook and loop attachment. The elastic band should be tight enough to prevent the pad from sliding out of place without restricting circulation.
- 6. Repeat steps 4 and 5 on the right side.

1 Center for Disease Control and Prevention, 27 Aug 2004, www.cdc.gov/neidod/hip/Sterile/laundry.htm



Laundering Instructions

#6018 / #60181-

Posey Hipster with High Durability pads are designed to withstand laundering in higher temperature hot washing cycles. Hipsters can be washed according to CDC guidelines for soiled linen. However, using the lower temperature washing and drying cycle for non-contaminated linen will prolong product life. "Studies have shown that a satisfactory reduction of microbial contamination can be achieved at water temperatures lower than 160°F if laundry chemicals suitable for lower-temperature washing are used at proper concentrations. In the home, normal washing and drying cycles including 'hot' or 'cold' cycles are adequate to ensure patient safety. Manufacturers instructions for the machine and the detergent or wash additive should be followed closely."

- Adhere hook and loop straps before laundering to prevent lint build-up on hook during laundry cycle. If hook and loop does not adhere due to lint, clean hook material with a stiff brush.
- If EZ On pads are removed, wipe clean with mild, liquid disinfectant before replacing in the pants.

Hipsters







High Durability Hipsters

y 82°C WASH HO 25 MIN

BLEACH AS DIRECTE ON CONTAINER DRY OF

Size	Waist Measurement		Hip Measurement	
5	28" - 30" or	71 - 76cm	35" - 37"	or 88 - 93cm
М	30" - 34" or	76 - 86cm	37" - 41"	or 93 - 104cm
L	34"- 38" or	86 - 96cm	41" - 45"	cr 104 - 114cm
XL	38"- 42" or	96 - 106cm	45" - 49"	or 114 - 124cm
XXL.	42"-46" or	106 - 116cm	49" - 53"	or 124 - 134cm

J.T. Posey Company

5635 Peck Road • Arcadia, CA 91006-0020 USA • Tel: 800-447-6739 or 626-443-3143 • Fax: 800-767-3933 or 626-443-5014 • www.posey.com @ 2004 J.Y. Posey Company. All rights reserved.



IDSS urckhardistr. 1, 0163. Hannover, Germany MG139

Document 156

Filed 12/11/2006

Page 7 of 7

AWARNING

Due to the random possibility of falls, the Posey Company makes no guarantee, express or implied, that the user is protected from hip trauma. The skin under the pants should be assessed regularly and Hipsters should be changed and washed after each incontinent episode to prevent skin breakdown.

Posey Hipsters contain foam pads that are sealed in a pouch to protect it from water. If the pouch is cut or the seal is broken during laundering, moisture will enter the pouch and may result in waterlogged foam. Waterlogged foam encased in the pouch may promote the growth of bacteria.

- · Test the foam and pouch integrity by squeezing the pad in one fist, forcing the air to one end, resulting in an air bubble
- · If you hear or feel liquid or air escaping, the pouch is damaged.
- · If the pouch is damaged, discontinue use and discard.

Clinical References Supporting the Use of Hip Protectors

Title: Author: External Hip Protectors to Prevent Osteoporotic Hip Fractures

A. Ekman, H. Mallmin, K. Michaelsson, S. Ljunghall The Lancet, volume 350, August 23, 1997

Publication:

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for hip fractures of the same magnitude as the previous report ."

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Prevention Of Hip Fracture in Elderly People

Pekka Kannus, M.D., Ph.D., et al

Publication:

The New England Journal of Medicine, Vol. 343, No. 21, November 21, 2000

Study Objectives: The purpose of this study was "to determine whether an external hip protector would be effective in preventing hip fractures among elderly adults." The study population was comprised of elderly adults from 22 community based health-care centers in Finland; a treatment group of 653 and a control group of 1,148 participants.

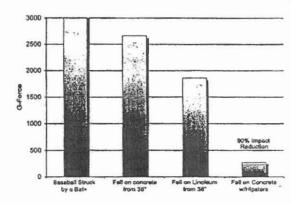
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Posey Hipsters Proven Effective in Laboratory Test

An independent laboratory study was conducted to determine the most effective impact absorbing material. A test was created that would simulate a fall causing direct impact to the greater trochanter. In this study, a weight was released in a guided drop to simulate a 120 lb. subject falling from a height of 36", or the estimated height of the hip above the floor for a typical nursing home resident. The baseline measurement of impact force was determined to be a fall directly onto concrete. The G-Force of a fall under this scenario was 2,660G's and, for purposes of comparison, is just slightly less impact force than that of a baseball being struck by a bat. In this extreme test, the low profile Posey Hipster reduced the impact force on average by 90% and showed excellent impact energy absorption.



Testing was conducted by Garwood Laboratories.

Data on file at J.T. Posey Company *Source: www.madsci.org

J.T. Posey Company, 5635 Peck Road, Arcadia, CA 91006-0020 • Phone 800-447-6739 • Fax 800-767-3933 • www.posey.com

Exhibit 15

UNITED STATES DISTRICT COURT FOR THE STATE OF MASSACHUSETTS

THE HIP SAVER COMPANY, INC.,

PLAINTIFF,

VS.

J.T. POSEY COMPANY,

DEFENDANT.

J.T. POSEY COMPANY, INC.,

COUNTERCLAIM PLAINTIFF,

VS.

THE HIP SAVER COMPANY, INC.; AND EDWARD L. GOODWIN,

COUNTERCLAIM DEFENDANTS.

NO. 05-10917 PBS

CERTIFIED **ORIGINAL**

CONFIDENTIAL

DEPOSITION OF VICTORIA LEWIS

CERRITOS, CALIFORNIA

THURSDAY, DECEMBER 15, Deponent:

.Signed transcript

Failed to sign transcript

Refused to sign transcript

Deposition officer:

COURT REPORTERS,

(800) 231-2682

MAILING ADDRESS

Orange County

920 W. 17th Street, Second Floor Santa Ana, CA 92706

Los Angeles 523 West Sixth Street Los Angeles, CA 90014

Central Coast 1610 Oak Street Solvang, CA 93463

REPORTED BY:

DENISE HERFT CSR NO. 12983

JOB NO.:

A0413NCV

UNITED STATES DISTRICT COURT FOR THE STATE OF MASSACHUSETTS

THE HIP SAVER COMPANY, INC.,

PLAINTIFF,

VS.

NO. 05-10917 PBS

J.T. POSEY COMPANY,

DEFENDANT.

J.T. POSEY COMPANY, INC.,

COUNTERCLAIM PLAINTIFF,

VS.

THE HIP SAVER COMPANY, INC.; AND EDWARD L. GOODWIN,

COUNTERCLAIM DEFENDANTS.)

DEPOSITION OF VICTORIA LEWIS,

TAKEN ON BEHALF OF THE PLAINTIFF, AT,

17871 PARK PLAZA DRIVE, SUITE 200,

CERRITOS, CALIFORNIA, COMMENCING AT

2:06 P.M., ON THURSDAY, DECEMBER 15, 2005,

REPORTED BY DENISE HERFT, CSR NO. 12983, A

CERTIFIED SHORTHAND REPORTER IN AND FOR

THE STATE OF CALIFORNIA, PURSUANT TO NOTICE.

APPEARANCES:

FOR THE PLAINTIFF/ LAW OFFICES OF

COUNTERCLAIM DEFENDANT: BROMBERG & SUNSTEIN

BY: EDWARD J. DAILEY

125 SUMMER STREET

BOSTON, MASSACHUSETTS

02210-1618

FOR THE DEFENDANT/ LAW OFFICES OF

COUNTERCLAIM PLAINTIFF:

SHELDON & MAK

BY: DOUGLAS H. MORSEBURG

225 SOUTH LAKE AVENUE

SUITE 900

PASADENA, CALIFORNIA

91101

THE VIDEOGRAPHER:

NANCY HOTALING

ALSO PRESENT:

ERNEST POSEY

1	BY MR. DAILEY:		
2	Q AND, AGAIN, I'M GOING TO ASK YOU TO TAKE A		
3	MOMENT TO REVIEW THIS DOCUMENT. DO YOU RECOGNIZE		
4	EXHIBIT 93?		
5	A YES, I DO.		
6	Q AND CAN YOU TELL ME WHAT IT IS?		
7	A IT IS A TEST REPORT FROM GARWOOD LABORATORIES.		
8	THE DATE ON MY TEST HAS A STAMP OVER IT, SO I DON'T KNOW		
9	THE DATE.		
10	Q CAN YOU READ UNDER IT? I APOLOGIZE FOR THAT.		
11	SOMEONE WROTE IT IN AN INOPPORTUNE PLACE.		
12	JANUARY 18, 2005; DOES IT LOOK LIKE THAT?		
13	A IT LOOKS LIKE THAT.		
14	Q OKAY. FINE. LET ME ASK YOU TO TURN, IF YOU		
15	WOULD, TO PAGE G 000119 IN THIS DOCUMENT AND IN PARTICULAR		
16	TEST 1 ON THAT PAGE "TABLE 1" ON THAT PAGE; DO YOU SEE		
17	THAT?		
18	A YES, I DO.		
19	Q AND DO YOU SEE WHERE IT SAYS THAT THE TEST		
20	INCLUDED A TEST OF SOMETHING CALLED "BEVELED PORON,		
21	STANDARD PORON, E.A.R., BLACK FLOOR MAT, POLYURETHANE		
22	FOAM;" IS THAT CORRECT?		
23	A YES, I SEE THAT.		
24	Q ANY OF THOSE PRODUCTS A HIP SAVER MATERIAL?		
25	A I DON'T KNOW.		
l			

1	Q	OKAY. WERE YOU INVOLVED, BY THE WAY, IN
2	PREPARATIONS	OF THE PROTOCOL FOR THIS TEST, THIS 2005
3	TEST?	
4	А	NOT DIRECTLY.
5	Q	DID YOU HAVE ANY INVOLVEMENT?
6	A	PRIOR PROTOCOLS WERE CARRIED OVER.
7	Q	OKAY. DID YOU OBSERVE THIS TEST?
8	А	I DON'T RECALL.
9	Q	OKAY.
10	А	I DON'T BELIEVE SO, BUT I DON'T RECALL.
11	Q	DID YOU PROVIDE THE MATERIALS FOR THE TEST?
12	А	I DON'T BELIEVE SO, BASED ON THE DESCRIPTIONS.
13	Q	OKAY. DO YOU KNOW WHAT PORON IS?
14	A	IT'S A FOAM.
15	Q	IS IT A FOAM THAT IS USED BY POSEY COMPANY?
16	А	YES, IT IS.
17	Q	AND IS IT THE FOAM THAT IS USED IN THE
18	HIGH-DURABII	LITY HIPSTER?
19	А	YES, IT IS.
20	Q	IS IT THE FOAM THAT IS USED IN WHAT HAS BEEN
21	MARKED AS EX	CHIBIT 87?
22	А	YES.
23	Q	YES, OKAY. AND WHAT COLOR IS THAT FOAM, IF
24	YOU KNOW, TH	HE PORON FOAM THAT'S USED IN THE HIPSTER?
25	A	THAT WE ARE CURRENTLY USING?

COUNTY OF	LIIFORNIA)
COUNTY OF)
	I AM THE WITNESS IN THE FOREGOING DEPOSITION
I HAVE READ	THE FOREGOING DEPOSITION AND HAVING MADE
CHANGES AND	CORRECTIONS AS I DESIRE, I CERTIFY THAT THE
SAME IS TRU	JE OF MY OWN KNOWLEDGE, EXCEPT AS TO THOSE
MATTERS WHI	CH ARE THEREIN STATED UPON MY INFORMATION OR
BELIEF, AND	AS TO THOSE MATTERS, I BELIEVE IT TO BE TRUE.
	I DECLARE UNDER PENALTY OF PERJURY THAT THE
FOREGOING I	S TRUE AND CORRECT.
	EXECUTED ON
	EXECULED ON
	, CALIFORNIA.
AT	, CALIFORNIA.
AT	, CALIFORNIA.

VICTORIA LEWIS .

REPORTER'S CERTIFICATE

I, LORI ODELL KENNEDY, CSR NO. 3320,

PRESIDENT OF KENNEDY COURT REPORTERS, INC., DO HEREBY

CERTIFY:

THAT THE FOREGOING DEPOSITION WAS TAKEN

BEFORE

DENISE HERFT

ON

THURSDAY, DECEMBER 15, 2005,

AT THE TIME AND PLACE SET FORTH, AND WAS TAKEN DOWN BY

HIM/HER IN SHORTHAND, AND THEREAFTER TRANSCRIBED INTO

TYPEWRITING UNDER MY DIRECTION AND SUPERVISION.

AND I HEREBY CERTIFY THAT THE FOREGOING DEPOSITION IS A FULL, TRUE AND CORRECT TRANSCRIPT OF HIS/HER SHORTHAND NOTES SO TAKEN, TO THE BEST OF OUR ABILITY.

I CERTIFY THAT I AM NEITHER COUNSEL FOR NOR RELATED TO ANY PARTY IN SAID ACTION, NOR IN ANYWISE INTERESTED IN THE OUTCOME THEREOF.

IN WITNESS WHEREOF, I HAVE HEREUNTO

SUBSCRIBED MY NAME THIS 3RD DAY OF JANUARY

20 06 .

LORI ODELL KENNEDY, CSR NO. 3320 CERTIFIED SHORTHAND REPORTER FOR THE STATE OF CALIFORNIA

EXHIBIT 16

CONFIDENTIAL, FILED UNDER SEAL

Exhibit 17

CERTIFIED COPY

UNITES STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

THE HIPSAVER COMPANY, INC.,	
Plaintiff,))
vs.) No. 05-10917PBS
J.T. POSEY COMPANY,))
Defendant.))
AND RELATED COUNTERCLAIM))

DEPOSITION OF EDWARD EBRAMZADEH, a witness herein, noticed by BROMBERG SUNSTEIN LLP, at 17871 Park Plaza Drive, Suite 200, Cerritos, California, at 1:46 p.m., Friday, November 10, 2006, before Diane M. Lytle, CSR 8606.

Hutchings Number 142014-NO



Т	APPEARANCES OF COUNSEL:
2	
3	For Plaintiff:
4	BROMBERG SUNSTEIN LLP
5	BY EDWARD J. DAILEY
6	125 Summer Street
7	Boston, Massachusetts 02110-1618
8	
9	For Defendant and Counterclaimant:
10	SHELDON & MAK
11	BY DOUGLAS H. MORSEBURG
12	225 South Lake Avenue, 9th Floor
13	Pasadena, California 91101
14	
15	Also Present:
16	Roger Jordan, Videographer
17	
18	
19	
20	
21	:
22	
23	
24	
25	

	1	Q. Okay.
	2	And I'm going to ask you to look at a document that
	3	has been previously marked as Exhibit 12. If you could
	4	just re-mark it as 12. [EXH-12]
	5	(Whereupon the document referred to is marked by
	6	the reporter as Plaintiff Exhibit 12 for
	7	identification.)
	8	MR. DAILEY:
	9	Q. Have you seen Exhibit 12 before or a document
14:43:24	10	that's similar to Exhibit 12?
	11	A. Yes.
	12	Q. And in particular, I'm going to ask you to look
	13	at the second page of Exhibit 12. And do you see the
	14	bottom third of the page or the bottom quarter of the
	15	page where the title is "Posey Hipsters Proven Effective
	16	in Laboratory Test."
	17	Do you see that?
	18	A. Yes.
	19	Q. And then if you read the second sentence under
	20	that it says, "A test was created that would simulate a
14:43:55	21	fall causing direct impact to the greater trochanter."
	22	Did I read that correctly?
	23	A. Yes.
	24	Q. Okay.
	25	Am I correct that in your supplemental report you
		46

HUTCHINGS COURT REPORTERS, LLC - GLOBAL LEGAL SERVICES 800.697.3210

- 1 state, in fact, that the Garwood test is not a valid
- 2 simulation of a fall?
- 3 A. Correct.
- Q. Okay.
- 5 So this statement that I just read to you is not
- 6 correct. Is that so?
- 7 A. Well, it's not a good simulation, but it's not
- 14:44:25 8 entirely false. They created the type of energy -- When
 - 9 I compare the energy impact -- impact energy, it was
 - 10 comparable.
 - 11 Q. So, Doctor, is it or isn't it, that's the
 - 12 question.
 - A. It's not a valid statement. It's not a --
- 14:44:55 14 Q. Okay.
 - 15 A. -- simulation of a fall.
 - 16 Q. Okay. Fine.
 - 17 A. Not a good simulation.
 - 18 Q. Okay. Fine.
 - And, in fact, if you look at Exhibit 163, and I'm
 - going to ask you to look at page HS2 002266.
 - 21 A. Yes.
- 14:45:28 22 Q. This is in your simulated -- this is in your
 - 23 simulated, I apologize.
 - 24 This is in your supplemental report --
 - 25 A. Uh-huh.

1 Q. -- and I'm going to ask you to look at the top of that page 2266. 2 3 Α. Uh-huh. And you state, since the Garwood test is not a 4 5 valid simulation, it should not be analyzed as one. 6 A. Correct. 7 Q. That's your statement and you stand by that 8 statement; correct? A. Yes. 9 10 Q. Okay. Fine. Is it fair to say that you and Dr. Hayes both agree 11 14:46:02 12 that the Garwood test is not a valid simulation of a 13 fall? 14 That's fair to say. Α. 15 Q. Okay. 16 Now, I mentioned this standard before, the ASTM standard F355-95; correct? 17 18 A. Correct. 19 Q. And is that a standard for conducting a simulated fall test? 14:46:33 20 21 A. No. Q. What is it? 22 23 Α. It's a test to compare different padding 24 materials for different purposes.

25

Q. Okay.

	1	can get it in the record, so bear with me.
	2	In opinion number 5 you state "The statement on the
	3	HipSaver website that the HipSaver airpad, 'reduced the
	4	force of impact from 7300 Newtons to 1790 Newtons
	5	that's more than 20% more force reduction than the
	6	hard-shell protection' is misleading and technically
	7	incorrect. The HipSaver reduced the impact force from
15:29:47	8	7300 to 1790 Newtons, that is, 24.5% of the impact force
	9	or a 75.5% reduction."
•	10	(Interruption in proceedings.)
	11	MR. DAILEY: Sorry about that. Equipment
15:30:17	12	malfunction, as they say.
	13	Q. "The Safehip reduced the impact force from 7300
	14	to 2240 Newtons, that is, 31% of the impact force, or
	15	69% reduction. The difference in percentage reduction
	16	is about 6.5%."
15:30:49	17	Did I correct that correctly?
	18	A. Yes.
•	19	Q. So from this you determined that when the
	20	HipSaver website says there was more than a 20 more
	21	than a 20 percent force reduction, that's an incorrect
	22	statement; correct?
	23	A. Correct.
	24	Q. Okay.
	25	Let me ask you to do the math this way. The

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- 1 impact --
- 2 MR. MORSEBURG: Are you going to play with
- 3 statistics now?
- 15:31:19 4 MR. DAILEY: I think we'll demonstrate that -- that
 - 5 Dr. Ebramzadeh knows how to play with statistics so
 - 6 let's go for it.
 - 7 Q. The impact force with Safehip is 2240; is that
 - 8 correct?
 - 9 A. Uh-huh.
 - 10 THE REPORTER: I'm sorry, "The impact"?
 - 11 MR. DAILEY:
 - 12 Q. The impact force with Safehip is 2240; is that
 - 13 correct?
 - 14 A. Yes.
 - 15 Q. Okay.
 - And the impact force with HipSaver is 1790; is that
 - 17 correct?
 - 18 A. Correct.
 - 19 Q. And the difference between the two is 450
- 15:31:49 20 Newtons; is that correct?
 - 21 A. Correct.
 - 22 Q. And if I express that difference as a
 - percentage by dividing 450 by 2240, can you tell me what
 - 24 the result is?
 - A. No, not -- not in my head.

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- 2 A. But I'll take your word for it that it comes
- 3 out consistent with that statement.
- 4 Q. About 20 percent; correct?
- 5 A. Yeah.
- Q. Okay.

- 15:32:19 8 difference in impact force between HipSaver and Safehip
 - 9 at the instant of impact?
 - 10 A. I would word it differently if I had done the

Does this percentage, 20 percent, represent the

- 11 calculation that way.
- 12 Q. Is that a proper calculation?
- 13 A. The calculation, you do it any way you want.
- The point is how do you word it? How do you present it?
- The way it's worded now, to me it makes sense to
- 16 calculate it the way I did.
- 15:32:50 17 Q. The way you did?
 - 18 A. Yes.
 - 19 Q. And not the way that I just did it?
 - 20 A. No.
 - 21 Q. Would you be surprised to know that the way I
 - 22 did it is exactly the way that Dr. Parkkari at Tempary
 - 23 does it?
 - 24 MR. MORSEBURG: Object. Assumes facts not in
 - 25 evidence. No foundation.

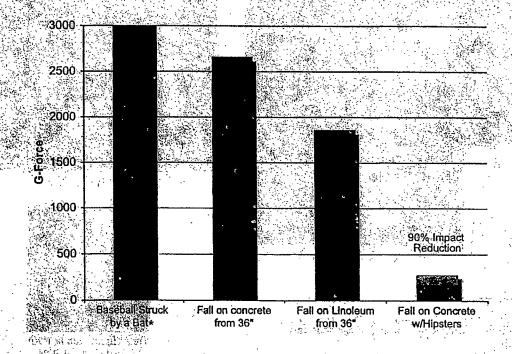
1	the deposition of Edward Ebramzadeh.
2	(The proceedings concluded at 3:33 p.m.)
3	
4	***
5	
6	I declare under penalty of perjury under the laws
7	of the State of California that the foregoing is true
8	and correct.
9	
10	Executed at, California,
11	on
12	
13	
14	EDWARD EBRAMZADEH
15	EDWARD EDRAMANDEN
16	
17	
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19	
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22	
23	
24	
25	

1	I, Diane M. Lytle, CS	R 8606, do hereby declar	re:
2	the foregoing deposition was	examined, the witness na as by me duly sworn purs	
3	to Section 30(f)(1) of the Procedure and the deposition	on is a true record of t	he
4	testimony given by the with	ness.	
5	That said deposition shorthand at the time and thereafter reduced to text		
7		ss was requested to revi	low tho
	transcript and	make any changes to the	
8		a result of that review ction 30(e) of the Feder	ral
9	Rules of Civil		
10	No changes have during the per	e been provided by the viod allowed.	vitness
11	· · · · · · · · · · · · · · · · · · ·	de by the witness are ar	
12	to the transcr		pended
13	reviewed pursua	made that the transcrip ant to Section 30(e) of	
1.4	Federal Rules	of Civil Procedure.	
1.5	I further declare that event of the action.	t I have no interest in	the
16	I declare under penal	ty of perjury under the	laws
17	of the United States of Ametrue and correct.	erica that the foregoing	j is
L 8	WITNESS my hand this	1st day of	
19	December	2006	
20	December		
21	Diane M. Lytle, CSR 8600	TRANSCRIPT CERTIFICATION	1800
22	Didie in Byele, Cok 8000		Opt a
23		TRANSCRIPT CERTIFICATION	
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25		SEAL	' rate of
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Exhibit 18

Posey Hipsters Proven Effective in Laboratory Test

An independent laboratory study was conducted to determine the most effective impact absorbing material as of July 2001. A test was created that would simulate a fall causing direct impact to the greater trochanter. In this study, a weight was released in a guided drop to simulate a 120lb subject falling from a height of 36", or the estimated height of the hip above the floor for a typical nursing home resident. The baseline measurement of impact force was determined to be a fall directly onto concrete. The G-Force of a fall under this scenario was 2,660G's and, for purposes of comparison, is just slightly less impact force than that of a baseball being struck by a bat. In this extreme test, the low profile Posey Hipster reduced the impact force by 90% and showed excellent impact energy absorption.



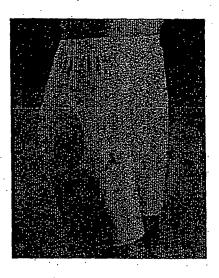
Testing was conducted by Garwood Laboratories, July 2001. Data on file at J.T. Posey Company
*Source: www.madsci.org

POSEY CA Care Alternatives Division

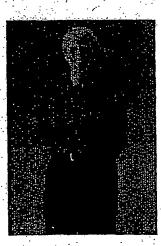
For more information or to place an order, contact your Posey District Manager or call 1-800-44-POSEY

PC 1026

POSEY HIPSTERS PROTECT AGAINST INJURY FROM FALLS

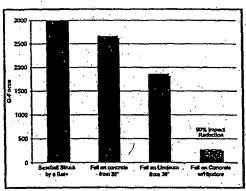


- It's a long way down for residents at risk of injury from falls. You can greatly reduce that risk with Posey Hipsters. The Hipsters' high energy-absorbing foam pads are positioned precisely over the hip bones. increasing the odds of surviving a fall uninjured. The Hipsters are comfortable and slim enough to be virtually undetectable under clothing. By offering increased protection, Hipsters relieve residents' anxiety about falling and enhance their quality of life.
- High impact-absorbing viscoelastic pads protect hip bones against injury from falls
- Soft, comfortable pads improve compliance versus hard-shelled products
- Washable to CDC standards for soiled linen without removing the pads
- 100% latex-free
- Five sizes for correct fit
- Discreet, low-profile pads are virtually undetectable under clothing



Low Profile -All styles fit discreetly under men's and women's clothing.

PROVEN IMPACT REDUCTION In an independent laboratory, simulating a fall from a height of 36 inches, the Hipsters reduced the impact force by over 90%.



Testing was conducted by Garwood Laboratories, July 2001. Data on file at J.T. Posey Company

POSEY CA Care Alternatives Division

PC 1074

special offer 30 day norisk free trial

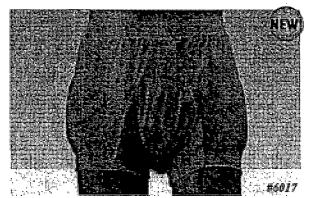
Jestahe Rosey Hipsters for yourself with no colligation to buy

FALL PREVENTION

POSEY HIPSTER III

Indications: Patients at risk for falling; those at risk for hip fracture.





Several studies have documented the efficacy of external hip protectors in preventing hip fractures. The Posey Hipster III features impact absorbing pads over the critical fracture area to help minimize potential damage, including hip fractures that can occur from a fall.

The brief is made from comfortable poly-cotton-Lycra® with a lowprofile pad positioned over each hip. These low profile pads are sewn into a slim fitting brief allowing the Hipster III to be discreetly worn under clothing. The one-piece design allows for easy home or institutional laundering.

Hipster III is available in two styles; standard unisex and incontinent models. The standard unisex brief easily slips on over undergarments or can be worn as underwear. The incontinent brief features a snap front for easier application over adult diapers. The Hipster III fits comfortably around the patient's waist and features a latex-free elastic waistband. 47% polyester, 47% cotton, 6% Lycra. Latex-free.

car.	STYLE STYLE					
6016 6017	Hipsters III Standard Brief (Replaces Posey #6010 unisex Hipster brief) Hipsters III Incontinent Brief (Replaces Posey #6011 Incontinent Hipster II brief)					
SIZE :	WAIST SIZE	HIPSIZE				
S M L XL XXL	28-30" 32-34" 36-38" 40-42" 44-46"	35-37" 39-41" 43-45" 47-49" 51-53"				



Low Profile - Both styles fit discreetly under clothing.

Posey Hipsters Proven Effective in Laboratory Test 1500 1000 Testing was conducted by Garwood Laboratories, July 2001, Data on file at J.T. Posey Company

An independent laboratory study was conducted to determine the most effective commercially available impact absorbing material as of July 2001. A less was created that would simulate a fall causing direct impact to the greater trochanter in this study, a weight was released in a guided drop to simulate a 120 lb, subject falling from a height of 36," or the estimated height of the hip above the floor, for a typical musting home resident. The baseline measurement of impact force was determined to be a fall directly onto concrete. The G-Force of a fall under this scenario was 2,660 G's and, for purposes of comparison, is just slightly less impact force than a baseball being struck by a bat. In this extreme test, the low purple Posey Hinster, III reduced the impact. In this extreme test, the low profile Posey Hipster III reduced the impact force by 90% and showed excellent impact energy absorption.

*Source: www.madscl.org.



Exhibit 19

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

The HipSaver Co. Inc.,

Plaintiff

v.

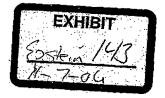
J.T. Posey Co.,

Defendant.

Civil Action No. 05-10917 PBS

Expert Report of Roy J. Epstein, PhD

September 25, 2006



I. INTRODUCTION AND SUMMARY OF OPINION

- 1. My name is Roy J. Epstein. I am an economist who specializes in economic and financial analyses, including expert testimony, in litigation matters. I have been an economics professor and economic consultant for over 20 years. Earlier in my career I held senior positions as an economist, principal, and director in several national economics consulting firms, including Lexecon, Analysis Group/Economics, and LECG. I now have an independent practice, based in Belmont, MA. I have a Ph.D. in Economics from Yale University. I have additional training in accounting and finance from the Graduate School of Business at the University of Chicago. From 1985 to 1989 I was an assistant professor of economics at the University of Illinois at Chicago. Since September 2003 I have been adjunct professor of finance at the Carroll School of Management at Boston College. In addition, I have served as an economic advisor on antitrust matters to the European Commission. A copy of my curriculum vitae is attached as Exhibit 1, which also contains a list of my publications in the past 10 years.
- 2. I have testified in federal court, before the Copyright Arbitration Royalty Panel of the U.S. Library of Congress, and in arbitration proceedings under the auspices of the American Arbitration Association. I have extensive experience in matters involving application of economic analysis to legal disputes, calculation of economic damages, and econometrics, which is the application of statistical methods to economic data. The testimony I have provided in the past four years is listed in Exhibit 2.
- 3. I have been asked by counsel for HipSaver to analyze the report submitted by defendant's experts Creighton Hoffman and Philip Green ("Hoffman/Green") on February 16, 2006 and to provide an independent assessment of damages to HipSaver in this lawsuit. I understand damages are claimed for allegedly false, misleading, and deceptive advertising circulated by defendant in connection with defendant's sales of "Hipster" hip protection garments. I am being compensated for my time at the hourly rate of \$375. Staff from Cornerstone Research, an economics consulting firm in Boston, working under my direction also assisted me in carrying out my analysis.

- 4. Exhibit 3 lists the materials I have considered to prepare this report. In forming my opinions I have also relied on my academic training in economics and finance as well as my professional experience as an economic consultant.
- 5. My conclusions can be summarized as follows:
 - Hoffman/Green's conclusion that Posey has not earned profits from Hipster sales is
 not correct. Messrs. Hoffman and Green only achieve this result by improperly
 allocating selling, general and administrative ("SG&A") expenses for Posey as a
 whole to the Hipster products. This allocation masks the underlying profitability of
 Hipster.
 - Positive profits for Posey's Hipster sales implies that disgorgement damages would
 also be greater than zero. Should Posey be found liable for damages by the court for
 the period August 2001 onward, I have calculated disgorgement damages of
 \$1,534,791. On the alternative assumption that Posey is found liable for damages for
 the period September 21, 2004 onward, I have calculated disgorgement damages of
 \$756,828.
 - There is insufficient information to calculate damages in the form of lost profits for HipSaver.
- 6. I have reached my conclusions with a reasonable degree of professional certainty. In the remainder of this report I explain the reasons for my opinions in more detail. I reserve the right, however, to amend my conclusions as new information becomes available.

II. ANALYSIS OF THE HOFFMAN REPORT

7. Hoffman/Green conclude there can be no disgorgement damages because they claim that Posey has not earned profits from Hipster sales. See Hoffman/Green at 8. More specifically, they state that Hipster has generated operating losses over the period January 2001 through December 2005 and also for the subperiod October 2004 through September 2005. See Hoffman/Green at 4. However, according to their own data, Hipster sales have exceeded the associated cost of sales by hundreds of thousands of dollars for every year over 2001–2005.

- The gross profit, in other words, is positive over this entire period. They arrive at their conclusion by assuming it is proper to deduct large additional costs that erase the gross profit.
- 8. An economically coherent calculation of disgorgement damages in this case should be based on the *incremental* profit earned by Posey as a result of the Hipster sales. This calculation would take the total Hipster revenue, on the one hand, and subtract the total costs incurred by Posey solely to make the Hipster sales. Cost of sales reflects such items as raw materials, direct labor, depreciation of plant and equipment used to manufacture Hipster products, and other direct production expenses. It is generally reasonable to subtract the cost of sales when calculating incremental profit and that is my opinion in this case. Hoffman/Green also subtract cost of sales.
- 9. The problem with the Hoffman/Green approach is that they further subtract a pro rata amount of Posey's aggregate SG&A expenses as if they were direct Hipster expenses. See Hoffman/Green at 8. They have provided no evidence that these expenses are attributable solely to Hipster. For example, managerial salaries, property taxes, and the expenses of running the corporate accounts payable department are all elements of SG&A that would be incurred regardless of the amount of Hipster sales or whether Hipster is even manufactured at all. In the absence of evidence that links the claimed SG&A allocation directly to Hipster, Hoffman/Green's inclusion of these expenses is a significant and unjustified downward bias to the incremental profit calculation.
- 10. I would agree with Hoffman/Green that it is appropriate to subtract Hipster-specific sales commissions and marketing expenses, if any, from gross profit because these items typically are not part of cost of sales. However, even if Posey includes these items in total SG&A, there is no basis to assume they can be accurately measured by using a pro rata allocation based on sales. Instead, I would expect the Hoffman/Green approach to overstate the Hipster-specific component of SG&A by a large amount. Moreover, it should not be necessary to resort to such guesswork since Posey should have been in a position to provide the relevant information directly.
- 11. In fact, Hoffman/Green appear to have performed no independent analysis of Posey's SG&A. The allocations they use are identical to documents prepared by Posey. See, e.g., PC 2893-

Page 6 of 33

- 98. Nonetheless, the problem remains that blanket allocations of common costs are not appropriate when determining incremental profit in the context of a damages calculation.
- 12. A simple example will illustrate the problem with the Hoffman/Green approach. In 2003 total Posey sales were \$34,443,351, of which Hipster comprised \$1,086,368, or 3.15%. See Hoffman/Green Exhibit D and Exhibit D-1. The Posey 2003 SG&A expenses were \$13,768,767. See Hoffman/Green Exhibit D. It is the nature of SG&A expenses in multiproduct firms like Posey, however, that many of them are common costs that have no particular association with a given product. For example, Posey's IT department in all likelihood provides services for every product line and administrative function. It is a common cost because the same IT resource, e.g., server hardware or support staff, is used throughout the firm. It is not specific to Hipster because even if the Hipster product line were abandoned the IT infrastructure would still remain in place. The product-specific costs in a multi-product firm cannot be identified by applying revenue-based allocations to the common costs.
- 13. Suppose, hypothetically, the Hipster-specific elements of SG&A in 2003 amount to \$100,000. The Hoffman/Green approach instead mechanically and unjustifiably allocates 3.15% of total SG&A, which in this case is \$434,277, to Hipster. See Hoffman/Green Exhibit D-1. Profits for that year would be understated by the excess SG&A allocation, or more than \$300,000 in this example.
- 14. The consequence of the Hoffman/Green analysis is that Posey would have been better off if it closed down the Hipster line in 2002, which is the last year with positive operating income according to their Exhibit D-1. This is not credible. The more credible explanation for the continued effort by Posey to manufacture and sell Hipster products is that it is in fact a significantly profitable activity. As I discuss in the next section of this report, the evidence in fact leads to the conclusion that Hipster has been profitable.
- 15. In sum, Hoffman/Green do not properly calculate profits because they improperly allocate SG&A expenses to Hipster. I consider this a fundamental economic error in the absence of

See, e.g., Michael Maher, Clyde Stickney, Roman Weil, and Sidney Davidson, Managerial Accounting, 4th edition (1991) at 178.

specific evidence that the costs they impute to Hipster are in fact specific to Hipster. For example, if Posey's president received a large salary increase in a given year, which would be recorded as part of SG&A, Hoffman/Green would charge a portion of that back to Hipster and find diminished profitability. They provide no independent evidence that their approach is accurate. The more reasonable conclusion is that their claim of zero Hipster profits is incorrect.

III. DISGORGEMENT DAMAGES

- 16. The starting point for calculating Hipster profits relevant for disgorgement damages is the gross margin. The information I have reviewed identifies only two other possible deductions from the gross margin. First are the Hipster-specific manufacturing variances identified in Hoffman/Green Exhibit D-1. Second are Posey's costs related to the prior litigation involving HipSaver. Absent any specific selling, general and administrative costs that are directly attributable to Hipster, no further adjustments to the gross profit are indicated.
- 17. While Posey's litigation expense can in principle be a deduction against profits for the period covered by that lawsuit, I have seen no direct evidence of the magnitude of this expense. The Hoffman/Green report implies total litigation expenses of \$1,116,407, although they provide no independent documentation to support this figure. See Exhibit 4. Case documents indicate that the settlement paid by Posey to HipSaver was \$360,000. See PC 0365. The implied legal expenses for Posey are the difference, or \$756,407. For this report I deduct the \$360,000 payment from the gross profit as the only verifiable litigation expense. If additional information is produced that verifies the Posey legal expenses, I will consider what further adjustments to my analysis are warranted.
- 18. I used the data in Hoffman/Green Exhibits D-1, D-2, and F as sources for the amount of Hipster sales. Copies of Hipster invoices were produced to HipSaver's counsel but the sales on those invoices appear to be far below the levels reported in Hoffman/Green. Since the Hoffman/Green data come from Posey financial statements and presumably also tie to Hoffman/Green's reported gross profits data, I think it is more accurate at this stage to use

- that information and not rely on the invoice data. If other, more reliable financial information is provided by Posey, I reserve the right to revisit this issue.
- 19. Counsel for HipSaver have asked me to prepare two alternative measures of disgorgement damages that correspond to two alternative liability theories. The first measure applies to a finding that Posey is liable for damages for the period August 1, 2001 to the present. My understanding is that August 2001 is the earliest known date of allegedly improper Hipster advertising. Data are only available through 2005, however, so this measure will be understated by omitting 2006. The second measure applies to a finding that Posey is liable for damages for the period September 21, 2004 to the present. Again, since data are only available through 2005, this measure will be understated by omitting 2006.
- 20. The damages using the first measure are \$1,534,791. See Exhibit 5. The damages using the second measure are \$756,828. See Exhibit 6.

IV. LOST PROFITS DAMAGES

- 21. I do not believe there are sufficient data to calculate lost profits damages for HipSaver reliably, even though there are indications of an effect of the challenged conduct on HipSaver's sales. For example, Hoffman/Green report that Posey's average monthly sales increased by 8.8% in the nine months following September 2004 relative to the nine months prior. See Hoffman/Green at 7. The same comparison for HipSaver, using data from Hoffman/Green Exhibit G, shows that HipSaver's sales increased by only 4.2%.
- 22. Nonetheless, other factors make it too difficult to measure lost profits reliably when data, as in this case, are limited. For example, I understand that product specifications were changing (see Hoffman/Green at 7). It is also my understanding that Posey has greater marketing resources due to its size and ability to offer other types of medical garments and equipment.
- 23. Moreover, no litigation-related surveys of Posey and HipSaver customers have been undertaken to determine directly whether actual purchasing decisions were influenced by the challenged conduct and the resulting implications for sales.

V. CONCLUSION

- 24. Hoffman/Green use an economically incorrect methodology by improperly allocating SG&A overhead expenses to Hipster as if they were direct expenses of production and sale. They artificially depress Hipster profitability to the point where they claim Hipster has lost money for Posey. This is not credible.
- 25. I find that Hipster has been profitable, so that disgorgement damages would be greater than zero. Given a finding of liability on the part of Posey from August 2001 to the present, I calculate Hipster's profits to be \$1,534,791 over this period. This is actually understated because data are available only through 2005. Alternatively, given a finding of liability for the period September 21, 2004 to the present, I calculate Hipster's profits to be \$756,828, again omitting 2006 for lack of data. If data for 2006 become available, I reserve the right to supplement my conclusions.
- 26. There is not sufficient information to perform a reliable calculation of HipSaver's lost profits as an alternative to disgorgement damages.

Roy J. Epstein

September 25, 2006

Exhibit 1

Curriculum Vitae

ROY J. EPSTEIN, PHD

34 Cushing Ave. Suite 200 Belmont, MA 02478

Tel. (617) 489-3818 Fax (928) 396-5627 Email: rje@royepstein.com

PRESENT POSITION

Economic Consultant, Independent Practice

Adjunct Professor of Finance, Carroll School of Management, Boston College

PRIOR POSITIONS

LECG, LLC, Cambridge, MA, 1999 - 2002 Director

ANALYSIS GROUP, INC., Cambridge, MA Senior Associate, Vice President and Principal, 1993-99

LEXECON, INC., Chicago, IL Economist, 1989-1993

UNIVERSITY OF ILLINOIS AT CHICAGO, College of Business Administration, 1985-89 Assistant Professor of Economics

EDUCATION AND PROFESSIONAL TRAINING

Ph.D, Economics, YALE UNIVERSITY. National Science Foundation Graduate Fellowship in Economics.

B.A., Economics, WESLEYAN UNIVERSITY. Magna cum laude.

UNIVERSITY OF CHICAGO, Graduate School of Business, Returning Scholar Program, Concentrations in finance and accounting.

CORNELL UNIVERSITY, Supercomputer Summer Institute.

SELECTED WRITINGS

Books

A History of Econometrics. Contributions to Economic Analysis 165. Amsterdam: Elsevier North-Holland, 1987.

Articles

"The Fall of OLS in Structural Estimation." Oxford Economic Papers 41 (1989), pp. 94-107.

"Anti-Trust and Higher Education: Was There a Conspiracy to Restrict Financial Aid?" With D. Carlton and G. Bamberger. Rand Journal of Economics 26 (1995), pp. 131-147.

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- "Anti-Trust and Higher Education: Was There a Conspiracy to Restrict Financial Aid?" With D. Carlton and G. Bamberger. National Bureau of Economic Research Working Paper No. 4998. (January 1995)
- "System Average Rates of U.S. Investor-owned Electric Utilities: A Statistical Benchmark Study." With E. Berndt and M. Doane. MIT Center for Energy and Environmental Policy Research Working Paper 95-005. (June 1995)
- "The Sensitivity of Least Squares to Measurement Error." (October 1998)
- "The Coefficient of Variation and Market Definition." (May 2000)
- "Patent Infringement Damages with Price Erosion: Using Economics to Extend State Industries v. Mor-Flo." (October 2001)
- "Economic Analysis of the Reasonable Royalty: Simplification and Extension of the Georgia-Pacific Factors." With Alan J. Marcus. (November 2002)

"Merger Simulation with Brand-Level Margin Data: Extending PCAIDS with Nests." With Daniel L. Rubinfeld. (August 20, 2003). Berkeley Olin Program in Law & Economics, Working Paper Series. Paper 89. http://repositories.cdlib.org/blewp/art89

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"Empirical Merger Analysis Using Simulation: New Developments in a New Field." Northeastern University, Department of Economics (January 2003).

"PCAIDS Merger Simulation with Nests: A New Framework for Unilateral Effects Analysis." International Industrial Organization Conference, Boston (April 2003).

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Sponsored Research

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Newspaper Columns

"Two Approaches to Seniors' Drug Benefits." With Ernst R. Berndt and Stan N. Finkelstein. Boston Globe Op-Ed. (February 20, 2001)

PROFESSIONAL SERVICE

Guest economic expert for the National Institute for Trial Advocacy (NITA) National Program in Boulder, Colorado.

Keynote speaker on measurement of patent infringement damages, American Intellectual Property Association Annual Meeting, Washington, D.C. (October 2003)

Member of the American Economic Association and the American Bar Association.

Journal referee and reviewer for:

U.C. Berkeley Electronic Press Econometric Theory

Energy Journal
Journal of Comparative Economics

Journal of Econometrics

Journal of Economic History

Journal of Economic Literature

Oxford Economic Papers

Review of Industrial Organization

Exhibit 2

Roy J. Epstein Deposition, Trial, and Written Testimony in Previous Four Years

AMERICAN ARBITRATION ASSOCIATION, SAN FRANCISCO, CA <u>Dapru Inc. v. NBSG. III. Inc and Sapphire Technologies</u>. Expert report, deposition testimony, and arbitration testimony in a claim of lost profits from an alleged breach of contract (2002).

UNITED STATES DISTRICT COURT, EASTERN DISTRICT OF PENNSYLVANNIA Tim Callahan d/b/a Tim's Sunoco Service, et al., v. Sunoco, Inc. and Sunoco, Inc. (R&M). Expert report and deposition on feasibility of computing class-wide damages (2004).

UNITED STATES DISTRICT COURT, EASTERN DISTRICT OF PENNSYLVANNIA Toledo Mack Sales and Service, Inc. v. Mack Trucks, Inc. Expert report analyzing liability and damages under Sherman Act and Robinson-Patman Act claims (2004).

UNITED STATES DISTRICT COURT, NORTHERN DISTRICT OF NEW YORK MapInfo Corp. v. Spatial Re-Engineering Consultants; SRC, LLC v. USAData, Inc. Expert report and deposition testimony analyzing damages in a claim of disparagement (2004).

UNITED STATES DISTRICT COURT, NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

Midwest Canvas Corp. v. Nationwide Tarps, Inc. d/b/a NTI Global. Expert report and deposition testimony analyzing damages in a claim of false and misleading advertising (2005).

UNITED STATES DISTRICT COURT, NORTHERN DISTRICT OF NEW YORK MapInfo Corp. v. Spatial Re-Engineering Consultants; SRC, LLC v. USAData, Inc. Second expert report and deposition testimony analyzing damages in a claim of disparagement (2005).

IN THE AMERICAN ARBITRATION ASSOCIATION

National Paintball Supply v. Paintball L.P. and Procaps L.P. v. National Paintball Supply. Expert report analyzing damages in a claim of improper contract termination (2006).

UNITED STATES DISTRICT COURT, DISTRICT OF KANSAS A/R Roofing et al. v. CertainTeed Corp. Expert report analyzing damages in a claim of disparagement (2006).

Exhibit 3

Materials Considered

Documents without Bates Numbers

Protective Order

Complaint dated May 4, 2005

Complaint dated July 26, 2005

First Amended Complaint

Amended Complaint dated December 2, 2005

Memorandum of Law in Support of Hipsaver's Motion to Dismiss "Contingent" Counterclaim

Plaintiff's Statement Concerning the Defendant's Revised "Laboratory Test" Advertising

Answer, Counterclaim and Request for Jury Trial

Response to JT Posey Company's First Set of Interrogatories

Answer to Counterclaim

Supplemental Response to JT Posey Company's First Set of Interrogatories

Expert Report of Creighton Hoffman and Philip Green dated February 16, 2006

Expert Report of Gary Reich dated February 16, 2006

Top 25 Nursing Home Chains

HipSaver vs. Posey Factors in damages

www.hiprotector.com

www.cdc.gov/ncipc/factsheets

Advertising, Conferences, Mailings

New Sales \$ for Each Advertising \$ Spent

Business Week, July 17, 2006, p. 52

Deposition Testimony

Edward L. Goodwin, October 18, 2005

Edward L. Goodwin, November 30, 2005

Edward L. Goodwin, March 3, 2006

Documents with Bates Numbers

HS2 000080-87

HS2 000130-32

HS2 00301 C-D

HS2 000324-26

HS2 000387-590

HS2 002074-98

PC 0365-73

PC 0406-7

PC 0809

PC 0852-54

PC 1468

PC 2893-2904

PC 2998-99

PC 3382-PC 5257

PC 3963

PC 5736

Electronic Documents

Hipster Invoices.mdb (containing data from PC 3963)

Hipsters Returns 2001-2005.xls (PC 5736)

Exhibit 4

Posey Litigation Cost Analysis

	2004	2005
Hipster Sales	\$1,322,561	\$1,461,801
As % of Posey Overall Sales	3.66%	3.55%
SG&A Expense - Posey Overall	\$17,497,091	\$17,015,654
Hipster Sales-Based SG&A Allocation	\$641,029	\$603,212
Hipster SG&A per Hoffman/Green Report	\$1,351,539	\$1,009,108
Implied Posey Lifigation Costs	\$710,510	\$405,896
Total Posey Litigation Costs	\$1,116,407	

Source: Hoffman/Green Report Exhibits D and D-1

Note: Hipster SG&A includes Posey I litigation costs in addition to allocated SG&A expenses.

Exhibit 5

Hipster Products Profit Analysis 2001–2006

		2001	2002	2003	2004	2005
	Sales	\$174,678	\$868,612	\$1,086,368	\$1,322,561	\$1,461,801
	Cost of Sales	\$77,052	\$519,712	\$669,935	\$819,921	\$835,862
	Gross Margin	\$97,625	\$348,900	\$416,433	\$502,640	\$625,939
	MFG Variances	\$3,797	\$3,785	<u>\$54,435</u>	\$28,940	\$5,789
	Effective Margin	\$93,828	\$345,115	\$361,998	\$473,700	\$620,150
,	Total Effective Margin	\$1,894,791				
	Verified Posey I Litigation Costs	\$360,000				
	Incremental Profit	\$1,534,791				

Sources: Sales Cost of Sales, and MFG Variances from Hoffman/Green Exhibit D-1; verified Posey I litigation costs from PC 0365.

Notes: 2001 pro-rated by 5/12 to reflect period starting August 1, 2001. Data for 2006 not available.

Exhibit 6

Hipster Products Profit Analysis September 21, 2004—December 31, 2005

Sales Revenue	\$1,836,499
Cost of Sales	\$1,065,683
Gross Margin MFG Variances	\$770,816 \$13,988
Incremental Profit	\$756 828

Source: PC 2904.

Note: Data for 2006 not available.

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

The HipSaver Co. Inc.,

Plaintiff

v.

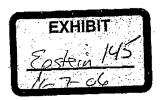
J.T. Posey Co.,

Defendant.

Civil Action No. 05-10917 PBS

Supplemental Report of Roy J. Epstein, PhD

October 31, 2006



I. INTRODUCTION AND SUMMARY OF OPINION

- 1. My name is Roy J. Epstein. I previously submitted a report in this case on September 25, 2006.
- 2. I have been asked by counsel for HipSaver to respond to the supplemental report submitted by defendant's experts Creighton Hoffman and Philip Green ("Hoffman/Green") on October 16, 2006. Supplemental Exhibit 1 lists the materials I have considered to prepare this report. In forming my opinions I have also relied on my academic training in economics and finance as well as my professional experience as an economic consultant.
- 3. My conclusions can be summarized as follows:
 - Hoffman/Green abandon without explanation their analysis in their February 16, 2006 report that calculates incremental Hipster expenses as a pro rata amount of Posey's total company-wide Selling, General, and Administrative ("SG&A") expenses.
 - Hoffman/Green abandon their earlier assumption that Posey's total SG&A expenses
 are a suitable basis for their analysis. They now use alternative SG&A data that
 exclude approximately 24% of the SG&A expenses from their first report. The
 implication is that approximately 24% of the SG&A expenses in the first report by
 their own reckoning are economically irrelevant to damages and should not have been
 used.
 - The regression analysis presented in their supplemental report as a new methodology
 for calculating incremental Hipster expenses from the alternative SG&A data is
 fundamentally invalid and misleading. Revising their model to address the most
 severe logical and conceptual deficiencies in their approach yields zero incremental
 Hipster expenses.
 - Hoffman/Green fail to disclose all of the data used in their regression analysis. They
 state they exclude the Posey I Settlement from the alternative SG&A data but
 nowhere do they identify the nature, magnitude, or timing of this expense. As I

- discussed in my first report, there is no basis to confirm or evaluate the adjustment for litigation costs they claim they make to their data.
- I see no reason to revise any of the conclusions from the report I submitted on September 25, 2006.
- 4. I have reached my conclusions with a reasonable degree of professional certainty. In the remainder of this report I explain the reasons for my opinions in more detail. I reserve the right to amend my conclusions, however, as new information becomes available.

II. HOFFMAN/GREEN'S SGA EXPENSE DATA

- 5. Hoffman/Green stated in their first report that they "allocated a share of Posey's total Selling, General, and Administrative expenses to the Hipster products on a pro rata basis with sales." The stated rationale was that this method, in addition to cost of goods sold, would capture all directly related costs of manufacturing and selling the Hipster products. See Hoffman/Green February 16, 2006 report at 8. In contrast, instead of total SG&A, the Hoffman/Green supplemental report considers "only [SG&A] cost centers related to sales of Hipster products, including engineering, sales and marketing and administration." See Hoffman/Green October 16, 2006 report at 5.
- 6. These measures of SG&A expenses are very different. Cumulatively, over 2001–2005, their first approach amounts to \$68,474,185. See Exhibit D to Hoffman/Green February 16, 2006 report. SG&A over the same period in their second approach is only \$52,256,040. Moreover, the gap between the two alternatives varies substantially year by year. See Chart 1.
- 7. Hoffman/Green's new SG&A figures still include many expenses that are unrelated to Hipster, despite their assertion that the data pertain to Hipster-related cost centers. Total Hipster sales over 2001–2005 were \$5,158,568 (see Exhibit D-1 to Hoffman/Green February 16, 2006 report). This is far below the new SG&A expenses, which exceed \$52 million. The new SG&A data evidently still consist predominantly of common costs or costs that are incurred by Posey regardless of the manufacture or sale of Hipster products.

8. In any event, Hoffman/Green now appear to imply that the SG&A expenses used in their first report are overstated with respect to Hipster. The implication is that their first report overstates incremental expenses, independently of the other problems I discussed with their pro-rata based analysis, and understates Posey's incremental Hipster profits.

III. THE HOFFMAN/GREEN REGRESSION ANALYSIS IS INVALID AND MISLEADING

- 9. Before discussing specifically how Hoffman/Green misuse the technique of regression, it will be helpful to provide a brief explanation of the potential relevance of regression analysis to the question of Hipster incremental costs. The basic problem is that Hipster-specific costs are not separately identified in the reported Posey SG&A expenses. Some other method is therefore necessary to determine what portion of the claimed SG&A, if any, is due solely to manufacture and sale of the Hipster products. A properly constructed regression model can be informative in this situation.
- 10. Regression analysis postulates that changes in one or more "explanatory" variables help determine changes in the value of a "dependent" variable. The technique uses the available data to quantify the independent effect of each explanatory variable in the form of regression "coefficients." Each coefficient measures by how much a change in the associated explanatory variable brings about a change in the dependent variable. For example, suppose the dependent variable was the price of an airline ticket and the independent variable was the distance flown. The coefficient on distance would measure the expected increase in the ticket price for each additional mile. In this example, the coefficient would measure the incremental price due to distance.
- 11. In addition, regression addresses the reliability of the results. It provides indicators for whether or not a given estimated coefficient is "statistically significant." A coefficient that is not statistically significant means the calculated value is likely to be the result of chance fluctuations in the data and that the true effect can reasonably be taken to be zero, i.e., no relationship with the dependent variable.

Filed 01/08/2007

- 12. In principle, regression analysis can address the question of estimating the Hipster incremental costs. However, there are many pitfalls. One of the most critical issues is that multiple factors are typically important in explaining a dependent variable. Omitting a relevant variable can then greatly bias the results. Returning to the airline ticket example, suppose the data included a mix of coach and first-class seats, as well as direct and connecting flights. It would probably be necessary to include these factors as additional explanatory variables in order to obtain an accurate coefficient for the pure effect of distance. A similar problem arises with the Hoffman/Green regression.
- 13. Hoffman/Green specify the dependent variable in their regression as the newly provided SG&A expenses, aggregated to a quarterly basis over the period 2001–2005. The sole independent variable in their analysis is quarterly total Posey revenue. To be clear, Hoffman/Green do not use Hipster sales as an explanatory variable so their analysis in itself does not demonstrate a relationship between Hipster sales and SG&A. Instead, Hoffman/Green merely assume that a coefficient for total Posey revenue accurately measures the independent effect just of Hipster sales.
- 14. The fundamental defect in their approach can now be seen. Their regression at best can only answer the question of the change in SG&A given a change in Posey's business as a whole. As I discussed in my first report, however, the bulk of the SG&A is incurred regardless of the presence or absence of Hipster. Moreover, Hipster is only a small fraction of Posey's total sales. It is irrelevant and inappropriate to estimate a coefficient that implicitly relates SG&A to a pro rata scaling up or down of the entire company. That approach does not identify the incremental SG&A due only a change in Hipster sales.
- 15. A proper regression model in this case must be formulated using at least two explanatory variables. For example, the first variable could be Posey's non-Hipster revenue and the second variable could be the Hipster revenue only. This formulation, unlike Hoffman/Green's, is capable of measuring the Hipster effect while simultaneously

When a relevant explanatory variable is omitted from a regression analysis, the estimated coefficients are generally biased and the tests of statistical significance are generally inaccurate.

- controlling for the effect of the other sales. Hoffman/Green's failure to allow for the possibility of a differential Hipster effect means their approach is biased.²
- 16. The bias in the Hoffman/Green approach is demonstrable and not merely a theoretical possibility. As part of their supplemental report they provide monthly data on SG&A and Posey's total sales. In Exhibit F to their February 16, 2006 report they provide monthly Hipster sales. This information is sufficient to correct the formulation of the regression model as indicated above.
- 17. The reformulated regression results are shown in Supplemental Exhibit 2. The coefficient for the Hipster revenue is negative, which would imply Hipster causes SG&A to decline. But an outcome such as this is one of the main reasons that regression also provides information on statistical significance. The estimated coefficient on Hipster revenue is not significant. The conclusion from the regression analysis is that the incremental effect of Hipster sales on SG&A expense is zero. In particular, Hoffman/Green's assertion that the relevant coefficient for Hipster revenue is 0.3733 (see Supplemental Exhibit D-3 to Hoffman/Green October 16, 2006 report) instead of zero results from their use of a biased statistical model.
- 18. Chart 2 presents the data for my reformulated regression graphically. The chart plots SG&A expenses from the Hoffman/Green supplemental report against Hipster sales after controlling for the effect of the non-Hipster sales. The general appearance evident in the chart of declining SG&A as sales increase is confirmed by the negative estimated coefficient on Hipster revenue. However, the chart also makes it clear that most of the data for Hipster are clustered in a pattern that displays no relationship to the SG&A. This, in essence, explains why the estimated Hipster coefficient is not statistically significant.
- 19. The corrected regression analysis therefore supports the findings in my first report in this case. Posey's incremental profits from the Hipster sales should be computed without any deduction for the SG&A expenses claimed by Hoffman/Green in either of their reports.

Other formulations of a regression analysis are possible and may be more accurate. The key is to allow for a separate effect due only to the presence of Hipster.

³ This is indicated by the magnitude of the "t-statistic" of 1.65 for Hipster.

⁴ Technically, this is a plot of the "residualized" value of SG&A against the "residualized" value of Hipster sales. See William H. Greene, Econometric Analysis, 2nd edition, at 179.

Filed 01/08/2007

20. A separate set of issues with the Hoffman/Green regression pertains to their data. They omit data for the 4th quarter in 2003, 2004, and 2005, i.e., in three out of the five years, without explanation. They also state that they exclude the costs of the Posey I settlement from the SG&A data but do not identify the nature, magnitude, or timing of the adjustment to the reported data. However, their regression model remains intrinsically biased regardless of the treatment of these data issues because it does not allow for an independent Hipster effect on SG&A.

IV. CONCLUSION

- 21. The Hoffman/Green supplemental report continues to employ an improper allocation of Posey SG&A expenses to Hipster as if they were direct expenses of production and sale. The method and data have changed from their first report but the underlying economic error remains. Before they simply assumed that a pro rata allocation of total SG&A based on sales could somehow identify incremental Hipster expenses. In their new report they instead assume that Hipster sales automatically generate additional SG&A expenses at the rate of \$0.3733 per dollar of sales. The new approach is based on an invalid use of the statistical technique called regression.
- 22. The Hoffman/Green regression model is invalid because it embodies the assumption that Hipster has the same effect on SG&A as an expansion of Posey's business as a whole. That is, it does not allow for an independent Hipster effect. This is not reasonable when many of the SG&A expenses are common costs or would be incurred regardless of the sales of Hipster. A corrected regression model using the available data shows zero incremental SG&A expenses as a result of Hipster sales.
- 23. I see no reason to revise the calculation of incremental Hipster profits presented in my first report as a result of the Hoffman/Green supplemental report.

Page 29 of 33

Roy J. Epstein

October 31, 2006

Supplemental Exhibit 1

Materials Considered

Documents without Bates Numbers

Expert Report of Creighton Hoffman and Philip Green dated February 16, 2006
Expert Report of Creighton Hoffman and Philip Green dated October 16, 2006
Expert Report of Roy J. Epstein dated September 25, 2006
Deposition of Charles Nail, December 15, 2005

Electronic Documents

Monthly SGA Expenses 2001 to 2005.xls

Supplemental Exhibit 2

Regression Estimation Results

SGA Expenses		
Coefficient	t Stat	
-9.14	1.65	
0.55	2.58	
398,795.5	0.58	
0.178	•	
24		
	Coefficient -9.14 0.55 398,795.5	

Note: Monthly data, January 2004 to December 2005.

Source: Exhibit F, Hoffman/Green February 16, 2006 Report and Monthly SGA Expenses 2001 to 2005.xls

Chart 1

Annual Posey SG&A Expenses in the Hoffman/Green Reports

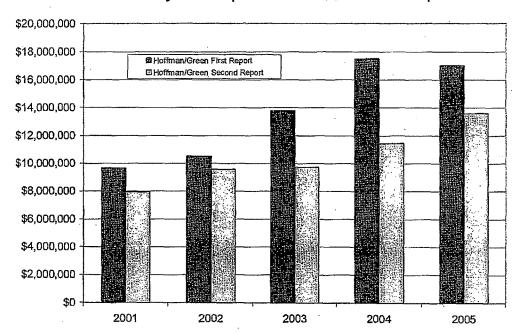
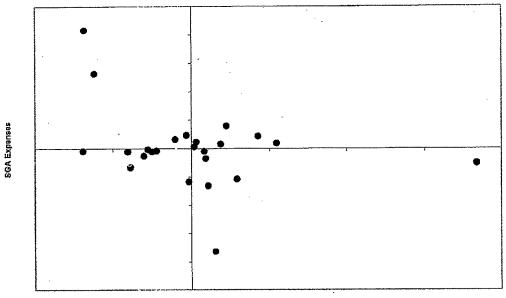


Chart 2

Plot of SGA Expenses vs. Hipster Sales



Hipster Sales

Note: variables measured after controlling for statistical effect of non-Hipster sales. Vertical axis measured as residual of regression of SG&A expenses on non-Hipster revenue, horizontal axis measured as residual of regression of Hipster revenue on non-Hipster revenue.

Exhibit 20

Video 2



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THATE 11-10-012

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Video 2: Hip Protectors in an Inpatient Setting

The video Hip Protectors in an Inpatient Setting is designed for nursing staff to raise awareness about hip protectors and their place in a falls prevention program. Nursing staff will learn about what is included in a falls prevention program, how to choose hip protectors for patients, how to size patients for hip protectors and instructions on how to wash hip protectors.

Audience: Nursing staff, including RNs, LPNs and NAs

Materials Needed: Hip protector information package (see following pages) and a
pencil or pen

001718

Hip Protector Information Package

Introduction:

This handout accompanies a video providing you with information about hip protectors so that, if decided, you can implement their usage at your VA medical center. This handout contains factual information as it is presented in the video, but is not a direct outline of the video. Use this handout as a supplement while watching the video or during follow-up discussions.

At the end of this handout is a section entitled Success Factors, which contains comments and opinions of teams who trialed different types of hip protectors on select patient units during an NCPS initiative called the Hip Protector Quality Improvement Project. This information does not appear in the video.

Implementing hip protectors can be challenging. Keep in mind that many VA medical centers currently use hip protectors and are eager to share their success factors.

General Information about Falls, Fractures, and Prevention:

- Hip fractures result from lateral falls with greater impact on trochanter or proximal femur.
- 3-5% of falls in older adults result in fractures and this percentage increases for inpatients due to prevalence of osteoporosis.
- Fractures lead to patient decline in functional ability and independence.
- About ½ patients who fall don't return to their previous level of functioning and 20-30% die within one year.
- Restraints are not effective fall prevention measures. They drain nursing resources, cause patients to lose muscle strength, and can potentially cause entrapment.
- VA wants veterans to be as mobile as possible and this means they may fall more often.
- Hip protectors reduce risk of serious injury from these falls.

001718 HS2 002200

Hip Protectors:

Hip protectors are designed to prevent trochanter fractures during patient falls.

Research studies show that hip protectors can significantly reduce patient injuries. Six studies found a lower risk of fracture in the patient group wearing hip protectors. Three of these studies reported no hip fractures while patients were wearing hip protectors.

Two manufacturers of hip protectors are HipSaverTM and PoseyTM.

There are several different models available by these manufacturers. These models are designed to meet the varying needs of different patients.

HipSaverTM Models

- SlimFitTM designed mostly for outpatients. The material is stretchy and form fitting. This model is also available with a male fly front.
- Nursing Home designed for nursing home patients. The material is less stretchy than the SlimFit model. It has larger leg openings so that it is easier for patients with less mobility. This model is also available with a male fly front.
- QuickChange™ designed for incontinent patients or for self-toileting patients who have difficulty moving the hip protector up or down. This model has two snaps in the front of the garment. This model is good for patients who are able to stand while they are being changed.
- Wrap&Snap™ designed for patients who are unable to stand while they are being changed, because the garment can be laid flat underneath them and snapped around them. Some self-toileting patients may also like this model.
- Open-BottomTM designed for self-toileting patients who are not able to pull the hip protectors up and down. The model is available with or without Velcro. The Velcro model can be wrapped around a patient, while the non-Velcro model is pulled up.

PoseyTM Models

- HipsterTM III (#6016) The standard model for continent patients.
- HipsterTM Incontinent (#6017) This model features a snap front for easy application while the patient is lying in bed.
- HipsterTM Fly Front (#6018) This model features a fly front and is white rather than the usual beige color.
- EZ On (#6019) This model is mesh and has a Velcro closure around the waist and each leg. It is designed for patients who may be at risk for falling while toileting or while in the shower.

001718

Monitoring Patients Wearing Hip Protectors:

- · Look for skin irritation, changes in patient continence, or signs of patient discomfort.
- · Adjust hip protector models and usage accordingly.

Laundering Hip Protectors:

The following laundry instructions may prevent the spread of hospital infections.

Washing Hip Protectors on the Unit

Wash with regular detergent and a small amount of bleach. Note: Dissolve bleach in water prior to putting hip protectors in the machine. Or, wash with detergent supplied by the laundry service for washing clothes on the unit. Dry at 160° Fahrenheit

Washing Hip Protectors in Hospital Laundry

Wash and dry in clothing/pajama's cycle. Use heavy soil cycle only as necessary

If using the hospital laundry, consider purchasing mesh laundry bags to ensure that the hip protectors stay together and are returned to the correct unit or facility. Mesh bags are also useful if laundry gets sent to another facility. Consider using special bins for the hip protectors so that they are always together. If you do this, make sure that the facility management and laundry people know what the bins are for and that they need to pick them up daily to ensure the hip protectors get washed in timely fashion.

HipSaver™ Laundry Notes

Choosing the right hip protectors is important for both the patients and the staff. Consider your laundry facilities prior to purchasing hip protectors. HipSaver™ hip protectors can be washed in hospital laundry facilities. Additionally, using small amounts of bleach does not degrade the products quickly. Drying temperatures should be low. The hip protectors should be removed promptly from the dryer, especially if using the hospital or a commercial/industrial laundry.

PoseyTM Laundry Notes

As a general rule, PoseyTM hip protectors should not be washed in the hospital laundry. They degrade more quickly and pads may crack or dissolve. Bleach appears to accelerate this degrading process. However, if necessary, small amounts of bleach

should be used. Hip protectors should be dried in low heat and removed promptly from the dryer.

If the hip protectors come with removable pads, then remove pads and wipe them clean using a mild, liquid disinfectant. The pads may be removable because they do not tolerate washing conditions well and may disintegrate.

Contact Manufacturers:

HipSaver™ Contact Information

Ed Goodwin	Helen Brogna	Phone: 1-800-358-4477
President	Vice President	E-mail: hipsavers@msn.com
HipSaver™ Inc.	HipSaver™ Inc.	Web site: www.hipsaver.com

PoseyTM Contact Information

Gary Platzman	Phone: 1-800-447-6739 extension 193
Vice President, Sales	E-mail: gplatzman@posey.com
Posey ^{тм} Company	Web site: www.posey.com

Wind the second of the second

Exhibit 21

Posey wash care labels: sewn into each Hipster



wash temp: 160°F maximum

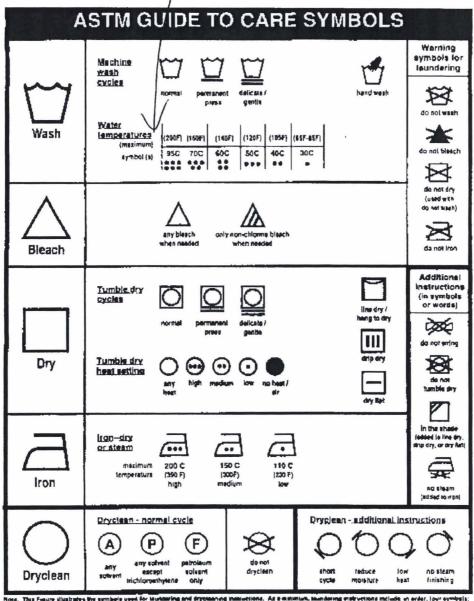


dry on low



Warning: No hip protector can protect against all injuries
Inspect garment and pads/pouches before each use
Discontinue use immediately if the foam appears misshapen, spongy, or the pouch is broken
Read instructions prior to use

HS2 000093



Note. This Fegure illustrates the symbols used for isothering and dependency indications. As a sixtimize, thendering embrections include in order, low symbols: wearing, blacking, drying, and symbols, and, drying, and, drying, and, drying, and, drying, and to charty the metricions include you symbol. Additional symbols are worth may be used to charty the metricions.

From FTC Regulations

Exhibit 22

CERTIFIED COPY

UNITES STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

THE HIPSAVER COMPANY, INC.,)
Plaintiff,)
vs.) No. 05-10917PBS
J.T. POSEY COMPANY,)
Defendant.))
AND RELATED COUNTERCLAIM)

DEPOSITION OF KEVIN G. MINISSIAN, a witness herein, noticed by BROMBERG SUNSTEIN LLP, at 17871 Park Plaza Drive, Suite 200, Cerritos, California, at 9:14 a.m., Friday, November 10, 2006, before Diane M. Lytle, CSR 8606.

Hutchings Number 142014-NO



800.697.3210 323.888.6300 FAX: 323.888.6333 • www.hutchings.com

1	APPEARANCES OF COUNSEL:
2	
3	For Plaintiff:
4	BROMBERG SUNSTEIN LLP
5	BY EDWARD J. DAILEY
6	125 Summer Street
7	Boston, Massachusetts 02110-1618
8	
9	For Defendant and Counterclaimant:
10	SHELDON & MAK
1 1	BY DOUGLAS H. MORSEBURG
12	225 South Lake Avenue, 9th Floor
13	Pasadena, California 91101
14	
15	Also Present:
16	Roger Jordan, Videographer
17	
18	
19	
20	
21	
22	
23	
24	
25	

- 1 question mark. 2 Did I read that correctly? Α. That's correct. 3 4 And is this your opinion below where you state, "In my opinion, this statement is false"? 5 6 Α. Yes. And did you render that opinion based on the 100 washings you did? 8 9 No. That opinion is based on my professional 10 opinion. 11 Q. Okay. I'm going to ask you to look at another exhibit. 12 13 And I'm going to ask that this be marked as the next in order Exhibit 155, and this is a document that is --14 15 Excuse me -- has a Bates number on the first page HS2
- 18 (Whereupon the document referred to is marked by
- 19 the reporter as Plaintiff Exhibit 155 for

of Kevin Minissian." [EXH-155]

20 identification.)

002222.

9:32:58

16

17

- MR. DAILEY:
- 9:33:37 22 Q. Take a moment to look at that.
 - Do you know what that document is?
 - 24 A. Yes.
 - Q. And what is that document, if you know?

20

And it's captioned "Supplemental Expert Report

	1	There's It's a full full guideline for laundry,
	2	people involved in the laundry industry.
	3	Q. And what in particular with respect to the wash
9:52:17	4	formulas did you review?
	5	A. They have a geri geriatric geriatric
	6	pads that also healthcare laundry facilities that
	7	utilize formulas from the textbook which every company
	8	involved in the industry utilizes these formulas.
	9	Q. Okay.
	10	And what did you do with those formulas?
	11	A. Nothing. I just I was asked to provide
9:52:48	12	information so I
	13	Q. To whom?
	14	A so I generated a document to Doug Morseburg.
	15	Q. What document did you generate to Doug
	16	Morseburg?
	17	A. The textbook and the other ones involved.
	18	Q. Okay.
	19	I think we'll come back to that in a few minutes,
	20	but why don't we press ahead. Would you go to the next
	21	page, which is has the Bates number HS2 02220.
	22	Do you see that? Do you see that page?
9:53:18	23	A. HS2, yeah.
	24	Q. Okay.
	25	The first document listed at the top is something
		. 36

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	1	Q. Does it Does it do institutional laundry for
	2	healthcare facilities?
	3	A. No. We use the facility to to We took
	4	one of their washers to do the test.
	5	Q. You rented time on one of their machines
9:55:20	6	A. Yes.
	7	Q is that fair to say?
	8	So a a washing machine and a drying machine?
	9	A. Yes.
	10	Q. Okay.
	11	Have you reviewed the documentation that is kept at
9:55:50	12	this laundry facility in El Monte?
	13	A. No, I have not.
	14	Q. Do you know whether or not the 100 cycles or
	15	any of the 100 cycles was, in fact, conducted in
	16	accordance with your protocol?
	17	A. It's in the The washer has a washer
	18	controller. It's a computer.
	19	Q. Yes.
	20	A. All the formulas are in that processor.
9:56:21	21	Q. All right.
	22	But have you reviewed it to see that it actually
	23	did what you thought it was going to do?
	24	A. I provided the information for my technician to
	25	do the test. I did not personally wash them.
		ર વ

1	Q. Did you go and review whether, in fact, your
2	technician had done the
3	A. I'd given the written copy for them to follow.
4	THE REPORTER: I'm sorry. I need you to wait for
5	the question to finish. I didn't get the last couple of
6	words.
7	THE WITNESS: Sorry.
8	THE REPORTER: I have "Did you go and review
9	whether, in fact, your technician"
10	MR. DAILEY:
11	Q had done the washing and drying in
12	accordance with your protocol?
13	A. No, I did not.
14	Q. Okay.
15	Did you give him a computer code?
16	A. He has the computer code.
17	Q. He has. Did you Did you verify that the
18	computer code included your protocol?
19	A. It's not a protocol. It's basically
20	washer's a microprocessor.
21	Q. Okay.

9:56:51

22

23

24

25

But does the microprocessor, whatever you want to call it, incorporate the wash formula guide used to wash Podey -- Posey products which you gave to Mr. Morseburg?

A. Yes.

40

	1	Q. So there's no inspection log; is that correct?
	2	A. The inspection logs are the facts what's in the
9:59:54	3	bag in the box.
	4	Q. There there are logs in the bag?
	5	A. No. There's signature of my signature on
	6	the on the bags, what they are, and what how many
	7	times they were washed, that's it.
	8	Q. Somebody told you they were washed 100 times
	9	and you signed your name; is that correct?
	10	A. That's correct.
	11	Q. So you don't know whether they
	12	A. My employees.
	13	Q. You don't know whether they were washed 10
	14	times, one time, 100 time, 1,000 times, do you?
10:00:24	15	A. My employees were instructed to do exactly what
	16	I told them.
	17	Q. Okay.
	18	And how did you confirm?
	19	A. I have the controller at the plant which tells
	20	me how many times the this formula was washed.
	21	Q. And what is the controller you're referring to?
	22	A. Microprocessor washer.
	23	Q. Okay.
	24	And tell me how that works.
	25	A. We have a specific formula that was made for
		44

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	1	Posey to wash these items.
	2	Q. Okay.
	3	And is that Let's stop right there. That
	4	specific formula. Is that written down someplace?
	5	A. It's in the controller.
	6	Q. Okay.
	7	How did it get in the controller?
10:00:57	8	A. My technician programmed it.
	9	Q. Okay.
	10	So you must have given your technician You must
	11	have given him or her some instruction; correct?
	12	A. That's correct.
	13	Q. What instruction did you give the technician?
	14	A. I give him the samples. I told him what they
	15	need to be done. I told him that they These are the
	16	formulas that he needs to put in the washer controllers.
	17	Q. So where are the formulas written down? That's
	18	what
	19	A. I don't have it with me.
	20	Q. Are they in your head?
	21	A. Yes.
	22	Q. Are they someplace else?
	23	A. No, they're they're in the computer. He's
	24	got them he's got them in the washer controllers.
	25	Q. Are they Are they in a textbook or a

10:01:27

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45

- 1 reference someplace?
- 2 A. Again, in -- it's in the microprocessor. It
- 3 has to be put on the paper.
- Q. You -- They've been inputted into the
- 5 microprocessor --
- 6 A. Right.
- A. That's correct.
- 9 Q. And apparently the microprocessor can somehow
- 10 print them out; is that correct?
- 11 A. No. We just go through it and handwrite it and
- 12 put them in a -- in a laptop and print it.
- Q. So there's a microprocessor someplace. What is
- 14 this microprocessor? Are we talking about a laptop or
- 10:01:59 15 what?
 - A. No, no. It's a -- It's a little microprocessor
 - that controls the cycle -- wash cycle of the washing
 - 18 machine. So you physically go there, enter the steps of
 - 19 wash cycle.
 - 20 Q. Okay.
 - 21 A. Temperatures, steam, drains, whatever. And
 - that microprocessor writes the formula the way you want
 - 23 to wash things. You put the product name, load size,
 - 24 how many pounds you're going to wash, and then you put
 - 25 the steps and temperatures and then -- then when you put

46

- the item inside the washer, close the door, you press the formula number, you start running until it finishes 2 10:02:29 and extracts. 4 When it's finished, then you take it out, put them in the dryer and dry it. Well, once you dry, bring it 5 back and wash it again. That's the way it was done. 6 7 Q. All right. 8 And where is there a record of what was entered 9 into that microprocessor? The technician has a copy that I told him to 10 11 enter into the microprocessor. 12 Q. Okay. 13 Again, for us it's a -- it's a very common 14 thing. We do this all the time. It's --15 Q. Right. But you were doing this as an expert witness; 16 10:02:59 17 correct?
 - 18 I was asked to wash the items.
 - 19 Were you -- Were you asked to do that as an 20 expert witness?
 - I'm not -- I don't know what you want to call 21 22 expert witness, but I was asked to wash and see if the 23 product will handle the wash formulas according to CDC 24 Guidelines.
 - 25 Q. Okay.

1 So I need -- I need you to tell me what the formula 2 is --Uh-huh. 3 Α. 10:03:29 -- or where it was recorded. And then I need 4 0. 5 you to tell me how that formula got into the computer 6 and that -- that was on the microprocessor on the 7 washing and drying machine, and then I need you to tell me how that was recorded so we know that, in fact, 100 8 9 cycles were done according to your formula. 10 Okav. Is there any record of that? 11 The controller keeps track of how many times 12 the formula was selected. 13 Q. Okay. The controller is on the machine? 14 Yes, on the -- on the machine. 15 Α. And can that be printed out? 16 Ο. 10:03:59 17 Α. You cannot print it out, but you can physically 18 see it. 19 You can physically see it. 20 After the 100 washings were done of the Posey 21 equipment, was that -- of the Posey product, excuse 22 me -- was that laundry equipment shut down so no more formulas were entered into the machine? 23 24 Α. They -- they use the washer every day. No, no. So how do we know -- Well, so how do we find 25 Q.

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48

- 1 what was done when your 100 cycles were done?
- 10:04:29 2 A. Formula has 31 formulas.
 - 3 Q. Yes.
 - A. Which they wash sheets, towels, pillow cases.
 - 5 There's extra formulas that are not being used. So
 - 6 he -- he took one of the formulas, made a Posey hip
 - 7 protector wash formula, so that formula was used to wash
 - 8 these items.
 - 9 Q. Okay.
 - 10 And how do we know that -- what formula of those 31
 - 11 he chose?
 - 12 A. What do you mean how -- how do you know?
 - 13 Q. Is there --
 - 14 A. A formula 5, formula 10, whatever he selected.
 - Q. But I'm asking you how do we know what he
 - selected? That's what I need to know.
- 10:04:59 17 A. Well, you're asking the question how do you
 - 18 know that things are washed right.
 - 19 Q. No, no. I'm on --
 - 20 A. No.
 - Q. No. I'm not even yet -- there yet. We got a
 - long way to go before we get there.
 - A. Yeah.
 - Q. I'm asking how do we know what the formula is
 - you gave to the technician, what formula he entered into

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	1	the computer, and what record there is to show that the
	2	formula he entered into the computer
	3	A. Uh-huh
	4	Q is the formula you gave him?
	5	A. Well, we can go verify.
	6	Q. And I'm asking you how do we verify that?
10:05:30	7	A. Just go look at the microprocessor.
	8	Q. Okay.
	9	And does the microprocessor have
	10	A. It retains memory.
	11	THE REPORTER: One at a time please.
	12	MR. DAILEY:
	13	Q. Does the microprocessor say on, for
	14	example, "February 13th, Posey load 1, 2, 3, 4, Formula
	15	X"?
	16	A. It does not give you a date. It gives you a
	17	number the formula number and a formula procedures.
	18	Q. Does it identify what was laundered?
	19	A. No, it just says "Posey item."
10:06:00	20	Q. It says "Posey item"?
	21	A. Yeah.
	22	Q. Okay.
	23	And does it list the formula?
	24	A. Yes.
	25	Q. Okay.

	1	And it's It has the chemical and wash settings
	2	and heat settings and so on and cycle
	3	A. That's
	4	Q times?
	5	A. That's correct.
	6	Q. Okay.
	7	So it will We can get that, we can extract that
	8	by looking into that record; is that correct?
	9	A. That's correct.
	10	Q. Okay.
	11	What's the technician's name?
	12	A. Jaime Gastelum.
	13	Q. Would you spell that?
10:06:30	14	A. Gastelum, G-A-S-T-E-L-U-M.
	15	Q. And first name?
	16	A. Jaime.
	17	Q. How do we spell that?
	18	A. J-A J-A-I-M-E.
	19	Q. And for whom does he work?
	20	A. He works for Norchem.
	21	MR. DAILEY: Can we take a break for a few minutes?
10:07:09	22	MR. MORSEBURG: Sure.
	23	THE VIDEOGRAPHER: We're going off the record. The
	24	time is 10:06.
	25	THE VIDEOGRAPHER: We are on the record. The time
10:15:01		51

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1	* * *
2	
3	I declare under penalty of perjury under the laws
4	of the State of California that the foregoing is true
5	and correct.
6	
7	Executed at, California,
8	on
9	
10	
11	KEVIN G. MINISSIAN
12	REVIN G. MINISSIAN
13	
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1	I, Diane M. Lytle, CSR 8606, do hereby declare:
2	That, prior to being examined, the witness named in the foregoing deposition was by me duly sworn pursuant
3	to Section 30(f)(1) of the Federal Rules of Civil Procedure and the deposition is a true record of the
4	testimony given by the witness.
5	That said deposition was taken down by me in shorthand at the time and place therein named and
6	thereafter reduced to text under my direction.
7	That the witness was requested to review the transcript and make any changes to the
8	transcript as a result of that review pursuant to Section 30(e) of the Federal
9	Rules of Civil Procedure.
10	No changes have been provided by the witness during the period allowed.
11	The changes made by the witness are appended
12	to the transcript.
13 14	XX No request was made that the transcript be reviewed pursuant to Section 30(e) of the Federal Rules of Civil Procedure.
15	I further declare that I have no interest in the event of the action.
16 17	I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.
18	WITNESS my hand thislst day of
19	
20	
21	Diane M. Lytle, CSR 8606 JACOURT REPORTS
22	
23	TRANSCRIPT B CERTIFICATION
24	
25	Diane M. Lytle, CSR 8606 TRANSCRIPT CERTIFICATION SEAL SE
	1 2 0

Vicky Walters

From: Sent: Sehulster, Lynne M. PhD [los0@cdc.gov] Monday, December 17, 2001 12:47 PM

To:

Vicky Walters

Cc:

Jemigan, Daniel B.; Katz, Susan B.

Subject:

Questions About Laundry

Vicky -

Your question has been referred to me. The draft Guideline for Environmental Infection Control and Prevention in Healthcare Facilities, 2001 was removed from our website after the comment period closed to avoid

confusion between that document and its final version (which will be available in the coming weeks).

Briefly, hot water temperatures for hospital laundries have been determined

by the American Institute of Architects' "Guidelines on Design and Construction of Hospitals and Healthcare Facilities" for several editions

now. The current edition repeats its statement about the need for water at

71 degrees C. for hot water washing. Cold water washing is permitted, and

if cold water laundering is selected it's important to use laundry detergents and additives that are developed for such applications. Water

temperature, as you might expect, is not a function of the washing machine

but rather the temperature of the water coming into the machine from the water mains.

We acknowledge the antimicrobial properties of hot temperature drying, not

to mention any ironing that is done. Since there have been virtually no cases of infectious disease transmission from clean hospital textiles, there

was no evidence on which to base specific recommendations for the temperature of the drying cycle or the length of the cycle that would enhance infection control. Additionally, because of the variety of fibers

and fabrics used in healthcare textiles, the parameters of the drying cycle

would vary greatly depending on the type of load being processed. And because of the many different makes and models of commercial dryers, the user is advised to follow the manufacturer's instructions for that machine

based on the load characteristics.

In addition to the AIA guideline, excellent resources for more detailed information about hospital laundering can be found at:

Riggs CH, Sherrill JC. Textile Laundering Technology. Textile Rental Service Association, Hallendale, FL; 1999: p. 92-97.

Association for the Advancement of Medical Instrumentation (AAMI) Processing of Reusable Surgical Textiles for Use in Health Care Facilities.

ANSI/AAMI Recommended Practice ST65: 2000.

Joint Committee on Healthcare Laundry Guidelines. Guideline for Healthcare

Linen Service. Textile Rental Service Association, Hallendale, FL, 1994.

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PC 0901

ORIGINAL STUDIES

Hip Protector Compliance: A 13-Month Study on Factors and Cost in a Long-Term Care Facility

Jeffrey B. Burl, MD, CMD, James Centola, PT, Alice Bonner, APRN-BC, and Colleen Burque, PTA

Objective: To determine if a high compliance rate for wearing external hip protectors could be achieved and sustained in a long-term care population.

Study Design: A 13-month prospective study of daytime use of external hip protectors in an at-risk longterm care population.

Setting: One hundred-bed not-for-profit long-term care facility.

Participants: Thirty-eight ambulatory residents having at least 1 of 4 risk factors (osteoporosis, recent fall, positive fall screen, previous fracture).

Intervention: The rehabilitation department coordinated an implementation program. Members of the rehabilitation team met with eligible participants, primary caregivers, families, and other support staff for educational instruction and a description of the program. The rehabilitation team assumed overall

responsibility for measuring and ordering hip protectors and monitoring compliance.

Results: By the end of the third month, hip protector compliance averaged greater than 90% daily wear. The average number of falls per month in the hip protector group was 3.9 versus 1.3 in nonparticipants. Estimated total indirect staff time was 7.75 hours. The total cost of the study (hip protectors and indirect staff time) was \$6300.

Conclusions: High hip protector compliance is both feasible and sustainable in an at-risk long-term care population. Achieving high compliance requires an interdisciplinary approach with one department acting as a champion. The cost of protectors could be a barrier to widespread use. Facilities might be unable to cover the cost until the product is paid for by third-party payers. (J Am Med Dir Assoc 2003; 4: 245–250)

Keywords: hip protectors; compliance; falls; costs and cost analysis; long-term care facilities

Hip fractures exact a heavy financial and human toll in the United States. More than 250,000 individuals sustain a hip fracture each year. Nearly 20% of those individuals die from complications of the fracture within 1 year, another 25% seek long-term placement, and less than half fully recover. ¹⁻⁸ Over \$5 billion is spent annually in direct and indirect hip fracture costs. ⁹⁻¹¹

Ninety percent of hip fractures occur in individuals over the age of 70. 12,13 Close to 2 million elderly, with a mean age

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of 84 years, reside in long-term care facilities. An estimated 4 million reside in the community with similar functional and medical impairments. This population of frail, at-risk elders has the highest potential for future hip fractures. 14,15

Several factors that potentially increase the risk for hip fracture have been identified. They include osteoporosis, low body mass index, and, most importantly, a sideways fall onto the greater trochanter of the proximal femur. 16-20 Multidimensional programs designed to reduce hip fractures have been reported, and most include reducing falls and fall risk factors, increasing bone density and muscle strength, and improving gait and balance. 21 However, some recent meta-analyses have reported limited statistical power to detect the effectiveness of specific strategies or programs to prevent falls and fractures. 22,23

Use of an external hip protection system that covers the greater trochanter of the proximal femur has been shown to reduce the incidence of hip fractures. 24-30 Yet, low compli-

ORIGINAL STUDIES

Burl et al. 245

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PC 0414

ance remains a major obstacle in the effective use of hip protector systems. ^{24,28,30-32} This 1-year study was undertaken to determine if moderate to high levels of hip protector compliance could be achieved and sustained in a long-term care facility.

METHODS

Subjects

Subjects were residents of The Masonic Home, a not-forprofit, 100-bed long-term care facility in Central Massachusetts. Eligible residents were ambulatory, with or without the use of an assistive device. High-risk residents were identified as having at least one of the following criteria:

- 1. Diagnosis of osteoporosis (T-score <2.5)
- 2. History of one or more falls within the past 6 months
- 3. History of prior fracture
- Positive falls screen on admission for residents admitted within the previous 3 months

Fifty-six long-term care residents met the criteria for participation in the hip protector compliance study. The enrollment period was continued from September 2001 through the end of December 2001 and ran through September 2002.

Study Design

All eligible participants were invited to attend a 1-hour educational session conducted by the medical director, the director of rehabilitation, and a physical therapist. This session explained the use of hip protectors, the potential risks and benefits, and the objectives of the study. At that time, any interested individuals were invited to participate and consent was obtained. Residents who agreed to participate at the initial meeting were measured for hip protectors (see "Equipment" section). For eligible residents with a diagnosis of dementia or other cognitive impairment, families received a letter explaining the use of the hip protectors, the potential risks and benefits, and the objectives of the study. Families of those residents were given the option of having the resident participate in the study, and consent was obtained from the appropriate family member. The medical director, the director of rehabilitation, and the physical therapist were also available to answer individual questions at any time.

One-hour inservice education sessions by the rehabilitation department were provided to all licensed nursing and Certified Nurse Aide (CNA) staff on the use of hip protectors, their potential benefits, the number of protectors each resident would receive, and how and when they should be worn. Although these sessions were not mandatory, most of the nursing staff did attend. The rehabilitation department met separately with those individuals unable to attend the sessions to explain the study.

Laundry and housekeeping were inserviced separately by the director of rehabilitation on the hip protector product, and the handling and laundering instructions (no bleach). They were informed of the total number of protectors that would be circulating through the department.

Equipment

A local Massachusetts manufacturer of soft hip protectors, the HipSaver™ Company, Inc., was contracted to provide the product. They were selected based on extensive discussions of various models, including results from the PACE Program (Program for All-Inclusive Care of the Elderly) in East Boston, which had successfully used this hip protector model for over 2 years. ³³ The Hip Saver Company in Canton, Massachusetts, was also selected because of close proximity to the study site and the ability to provide comprehensive customer service:

The hip protector company provided inservice education to the department of rehabilitation on measuring residents for proper size, ordering, and laundering requirements. They also provided a sizing chart, and all subjects were subsequently measured and fitted by the rehabilitation department for the proper-sized protector (there were 4 possible sizes). A measurement was performed around the widest circumference of the pelvic region.

After discussions with the nursing, rehabilitation, and laundry departments, it was determined that 4 sets of protectors would be dispensed to each resident to ensure that a hip protector would be available when needed. The rehabilitation staff was responsible for ordering the protectors and marking them with the resident's name before distribution. The nursing staff was responsible for distribution and storage on the nursing units. The cost of each hip protector, at the beginning of the study, was \$30.

Tracking Compliance

For the purposes of this study, any individual who wore the hip protector at least once and was able to be monitored for a minimum of 9 months was included. It was felt that a longitudinal follow up was essential to determine if consistent wearing of the hip protectors could be maintained over time. Only daytime hip protector use was evaluated (ie, use from the time the resident was dressed in the morning until they were in bed for that night). Nursing staff received the protectors and distributed them to the appropriate residents. Those with activities of daily living deficits were given reminders by the CNAs and staff assistance in donning the protectors when needed.

Percent compliance was measured monthly by dividing the total days hip protectors were worn by the number of days in the month. Nursing tracked daily compliance on a log created and kept in the medication administration record (MAR) on the medication cart. At the time of the medication pass, the CNA reported to the nurse whether the resident had worn the hip protector for that day. The nurse noted this in the study log. Nursing was interviewed monthly by a representative from the rehabilitation department to obtain ongoing compliance data in the study subjects. The rehabilitation department reviewed the monthly tracking record and recorded monthly compliance for each resident. Compliance data was recorded for a total of 13 months.

Table 1. Demographic Characteristics

Characteristic	N/%
Average age (y)	89
Mode	· 93
Percent female	75%
Medicare	86%
Medicaid	92%
1 risk factor	39%
2≥ risk factors	61%

RESULTS

Fifty-six long-term care residents met the inclusion criteria for the study. Five residents agreed to participate when initially approached by the medical director, but refused to be measured and were not issued the hip protectors. These residents were not considered to be in the study. Six residents died, and an additional 7 had a significant change in condition to nonambulatory status well before the 9-month minimum could be completed. These 2 subgroups were not included in the data. Thirty-eight residents completed at least 9 months of the 13-month trial, with a mean follow up of 11.9 months. Data was collected on a total of 38 residents.

The average age of study participants was 89.5 years, with a mode of 93 years. Seventy-five percent of the participants were women, and 78% had a primary diagnosis of dementia. Ninety-two percent of participants were on state medical assistance (Medicaid) and 86% had Medicare coverage for part A expenses. More than half of the participants had 2 or more risk factors, and approximately one third had only one risk factor (Table 1). The total number of medications per resident did not change significantly during the study. The total scheduled psychoactive medications averaged one medication per participant (Table 2).

During the 13-month study period, a total of 206 falls occurred in the facility, averaging 15.8 falls per month or approximately 1.5 falls per resident per year. One hundred twenty-six of the falls (61%) involved 34 of the 38 study participants, or one-third of the total 100-bed nursing facility population (average occupancy, 98.9). Mean number of falls per participant was 3.9, compared with 1.3 falls for those not in the study. There were 2 hip fractures in the facility in the year before the start of the study. There were no hip fractures in the facility during the 13-month intervention. There were 5 non-hip fractures during the study, 2 fractures (clavicle,

Table 2. Prestudy and Poststudy Average Medications

Average Medications Per Participant Per Day	Start of Study	End of Study	Paired t-test	P Value
Total medications	7.75	8.06	551	.59
Cardiac medications	1.14	1.17	177	.86
Total psychoactives	0.94	1.08	-1.54	.13
Antidepressants	0.47	0.53	-:81	.42
Antipsychotics	0.22	0.25	-1.43	.16

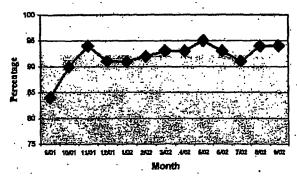


Fig. 1: Percent hip protector compliance from September 2001 through September 2002.

humerus) in 1 individual. Three of the 4 individuals who sustained a non-hip fracture were in the study group. Two subjects sustained fractures during the night (pelvis, rib) when they were not scheduled to wear the hip protectors. The other subject sustained a forearm fracture from a fall. She was wearing hip protectors at the time of the fall. By the third month of the study, average compliance exceeded 90%, and this was sustained for the remainder of the study (Fig. 1).

CNAs were interviewed by the rehabilitation staff in cases of noncompliance and were asked why hip protectors were not being worn. Most often, CNAs reported that the individuals were not wearing the hip protectors because of acute illness (not expected to get out of bed that day) or possibly as a result of laundry issues (occasional difficulty getting protectors back from laundry on Mondays, according to CNAs). Another reason given was that the resident was going out to see a specialist (medical or surgical), where the use of hip protectors was felt to be an added burden during the appointment. By the third month of the study, residents (those not requiring help with activities of daily living) appeared to consider the protectors part of their daily dressing routine and, for the most part, only required minimal cues from CNAs. Two participants were hip protectors regularly for the first month of the study, but reported that they were not comfortable. Despite size changes, these subjects elected not to continue the hip protectors but were counted in the compliance

Staff time spent in the initial phase of the study on educational sessions for the residents and staff was 7.75 hours, for an estimated indirect cost of approximately \$500. Total cost for the hip protectors for the 49 participants who agreed to be measured was \$5880, for a total direct and indirect cost of \$6300 for the study. None of the 6 deaths were related to a fall, and were not related to the use of hip protectors. The average time that hip protectors were worn by the 7 subjects who had a change in condition was 1.8 months (range, 1-4 mo). Average compliance for this group was 55% (range, 35-75%). The average time that hip protectors were worn by the 6 subjects who died was 3 months (range, 0-7 mo). The average compliance was 93% (range, 67-100%).

ORIGINAL STUDIES

Burl et al. 247

DISCUSSION

The incidence of hip fractures is expected to significantly outpace the growth of the senior population in the coming years. Between 1970 and 1997, the Finnish population over age 50 increased by 53%, whereas hip fracture incidence increased by more than 169%. The total number of hip fractures worldwide is predicted to more than quadruple from 1.6 million to more than 6.2 million by 2050 if nothing is done to prevent this potential health crisis. 34

Although the incidence of falls in long-term care is 1.5 falls per bed per year, ^{24,35,36} only 1–2% of all falls result in a hip fracture. ^{37,38} Studies have shown that the major causal factor for hip fracture is an impact to the greater trochanter, in which the impact energy of a fall exceeds the average fracture threshold of the proximal femur. ^{16–20} In addition, studies have demonstrated that osteoporosis, low body mass index, and height of a fall are independent risk factors for hip fracture. ^{16–20}

Successfully reducing hip fracture rates requires an interdisciplinary process in which all risk factors are addressed. To date, efforts to reduce falls, improve gait and balance, and increase body mass index have met with only partial success. Treatment of osteoporosis with antiresorptive medications might only increase femoral neck density by 2% per year, 39 which might not be sufficient for fracture reduction in longterm care residents whose average life expectancy is approximately 24 months. 15 One preventive strategy that could potentially reduce the impact energy of a fall to the greater trochanter is the use of external hip protectors, an external padding system that both absorbs and shunts energy away from the proximal femur. Studies have demonstrated the effectiveness of hip protectors, with one estimate that hip fractures could be reduced by 60% in those wearing the device, and up to 80% if all residents were the protectors. 28

Two recent studies have questioned the efficacy of hip protectors. In a randomized, controlled trial with 18 months of follow up, Meyer showed a relative reduction in hip fracture of more than 40%, but at borderline significance. To van-Schoor randomized a mixed group of community-dwelling elderly and nursing facility residents in a '16-month study. No statistical difference between the control and study groups was realized. However, the authors noted a 23% nonsignificant reduction in hip fractures in individuals who were the hip pads, as well as a lower fracture rate per fall in the study group. A

The definition of compliance is not standardized, making comparisons between studies problematic. Several studies report compliance only at the time of a fall, as opposed to reporting total number of days of fracture protection per patient. Lauritzen et al. base their compliance reporting on fall registers, ie, the number of times the resident was wearing the hip protectors at the time of the fall with a compliance rate of 24%. Two other studies using similar compliance measures had rates of 46%, and 54%, respectively. 15,30 Harada, using a case-controlled observation method, noted a compliance rate for complete and incomplete wear in 88 subjects of 70% and 17%, respectively. 26 vanSchoor, using a

self-reporting mechanism, found compliance of 45% at 6 months and 37% at the end of 12 months.⁴⁰

The reasons for low compliance in these studies are not described in detail; however, study design could be one factor. Individuals are often asked to wear hip protectors without the staff having had detailed education regarding their use. Thus, lack of staff understanding and support could have been a factor in some studies. Hip protectors are most likely to be of benefit with maximum daily wear. Based on Parkkari's framework, 41 a structured educational program for both staff and patients was instituted in this study. The intent was to have staff support and encourage the use of the hip protectors. In addition, the concept of daily wear count was used in determining compliance. Each day the CNA provided feedback on hip protector wear, which was documented in the MAR. This was felt to be a more accurate assessment of total hip protector wear and fracture prevention. In our study, residents with a significant change in condition or decline in functional status had lower compliance than the other subjects (55%). One explanation for the low compliance in this group is that when patients become acutely ill, staff determines other care issues to be of higher priority. Also, when patients spend more time in bed, for example when acutely ill, CNAs might elect not to use hip pads. This specific topic might require dedicated inservice education.

Based on the results of this study, it appears that relatively high compliance is feasible and potentially sustainable in a long-term care facility. Compliance after the third month did not drop below 90%. This could have been attributable in large part to the rehabilitation department's role as a champion as well as the formal educational component of the study. There were 2 individuals included in the compliance who could not wear the hip protectors as a result of poor fit. Despite repeated attempts to optimize fit, the individuals complained of discomfort. If we exclude these 2 subjects from the data, average daily compliance exceeded 95%.

Failure to achieve higher compliance in the first 3 months could have been the result, at least in part, of issues with laundering of the protectors. Because of limited laundering on the weekends, especially for the incontinent residents who needed frequent changes, clean hip protectors might not have always been available on Monday mornings. This was resolved by providing those residents with 2 additional sets of protectors. One positive finding was that CNAs who had received the educational session would often call the rehabilitation department to obtain hip protectors before getting residents out of bed, if none were available in the patient's room. The CNAs reported occasionally borrowing unused/ unopened hip protectors from other residents in an emergency, rather than getting a resident out of bed without them. For continent residents, 3 sets of hip protectors might besufficient. However, incontinent residents might need more than 4, depending on the frequency of laundry services. Previous studies have not always reported the number of pads dispensed per resident. In some studies, only 2 or 3 protectors per resident were used. It is possible that the higher compliance rate in this study was, in part, related to the relatively high number of pads dispensed to each resident.

Kannus estimated that 42 individuals would need to be treated for 1 year to prevent one hip fracture. 28 Given the compliance and number of users in the current study, approximately 1–2 hip fractures per year could be prevented. This could represent a potential cost savings to Medicare of approximately \$20–40,000 (Fallon Community Health Plan, unpublished data). 11,42

One major barrier to the use of hip protectors is the cost of the product. Until Medicare and Medicare + Choice programs provide external hip protectors as a covered benefit, either facilities or residents/families will be responsible for purchasing the protectors. Given the current budget crisis in many states, long-term care facilities are likely to face reductions in per diem rates. As of March 1, 2003, Massachusetts has reduced Medicaid payments to nursing facilities by over 2%, with possible further reductions. Facilities are faced with trying to maintain quality of care despite decreased revenue, and might be less likely to offer hip protectors to high-risk residents, unless they perceive some indirect benefits to the facility as well as to the resident. Some of those indirect benefits might include improved facility quality ratings, fewer reports of hip fractures to state authorities, and improved state survey results with regard to fall prevention. As more studies demonstrate the effectiveness of external hip protectors in preventing hip fractures in targeted populations, state or federal regulations might change to require hip protectors for certain high-risk, long-term care residents.

CONCLUSION

High compliance rates for hip protectors in an at-risk, long-term care population are feasible. Success depends in part on whether there is broad-based acceptance by support staff, especially CNAs, who can make the hip protectors an integral part of the daily routine for each resident. The process also requires a champion, a person or team, to assume accountability not only for measuring compliance, but also for attending to small details such as measuring, ordering, marking, and storing the hip protectors. In this study, the department of rehabilitation provided the leadership and accountability to sustain the program. Elder advocates and lobbyists need to inform federal and state governments of the potential benefits of hip protectors. Pending further research, insurers should be encouraged to provide them as a covered benefit to targeted, high-risk patients.

ACKNOWLEDGMENTS

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Document 183-31

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HIP PADS: EFFECTIVE FRACTURE PREVENTION Simple intervention can reduce the risk of falls resulting in hip fracture

By George Gross, PT, Tsan-Hui Chen, OTR/L, Carolyn Flaherty

Falls are a serious problem in the elderly. One of the most significant consequences of falls is hip fracture, caused by the sudden transmission of a large, mechanical load, which damages tissues and cells. If this energy load could be dissipated over a larger area, injury could be prevented. This review examines the results of a program that used hip pads in community dwelling, frail elders and found impressive results in hip fracture prevention. There was a hip fracture rate of 0 in the study population compared to a rate of 4.3 percent in the control population. Fisher's exact test analysis comparing these results yields a P=0.00089576 and a highly significant difference.

This study examines the results of a program at the Elder Service Plan of East Boston that used HipSavers for patients with histories of frequent falls to absorb and dissipate the energy transmitted in a fall to prevent hip fractures. HipSavers are underpants with soft thin pads of laminated, shock absorbing elastomers covering each trochanter

Fall Statistics

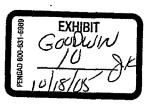
Falls are a major health hazard in the elderly. One-third of all elders older than 65 years of age fall at least once a year. ¹⁴ Loss of independence often follows a fall. Falls are a factor in 40 percent of nursing home admissions. ⁵ The more frequently falls occur, the greater the likelihood of mortality and morbidity for the older adult. ⁶ Fall related injuries are the leading cause of death from injury in people over 65. ^{1, 7} Only 50 percent of individuals admitted to hospitals as a result of a fall will be alive in one year. ^{3, 8}

Ten percent of falls in the elderly result in serious injury and 5 percent result in some type of fracture.^{4, 8} The rate of hip fracture as a result of falls in the elderly has been calculated between 1 percent and 2.9 percent.^{2, 7, 10} Hip fractures are one of the most catastrophic, life changing and life threatening consequences of falls and frequently result in decreased mobility and loss of independence in older adults.³ Hip fracture is the most common among all injuries leading to hospital admissions in the United States¹¹ and is a contributing factor in 40 percent of admissions to nursing homes.^{3, 12} One-quarter of these patients die within six months of injury and of those remaining alive, 60 percent have decreased functional mobility and 25 percent remain functionally dependent after a hip fracture.¹³

Rehabilitation after a hip fracture is expensive in emotional and social as well as financial costs. The Center for Disease Control and Prevention statistics for 1994 report 243,000 hip fractures per year. The cost of caring for older patients with hip fractures is \$2 billion annually. Falls pose a particular problem for public health professionals in the development of both surveillance systems and prevention strategies. Most falls do not result in serious injury and are therefore not reported. The absence of injury probably accounts for the poor reporting of falls and underestimation of the problem. Adler-Traines views injuries as predictable events that have remedial behavioral and environmental antecedents. Therefore, they can be reduced in number and severity by proper interventions.

Prevention Strategies

Effective fracture prevention strategies can be cost effective and beneficent interventions. Identifying patients at risk permits interventions aimed at reducing both intrinsic and extrinsic risk factors for falls and fractures. Falls are multifactoral. The primary goal is treatment of the problem or the cause to effect clinical change. If change is not expected, the course of action is compensation. For certain patients, the risk of falling remains great despite preventive measures. For these patients, the use of padded undergarments to absorb the impact of a fall and thereby reduce the risk of a hip fracture from a fall has been advocated. Sattin views injury as a disease with a short latency period. In a fall, a large mechanical energy load is quickly transmitted and damages cells and tissues, potentially resulting in a hip fracture. If the same energy load could be transmitted at a slower velocity or dissipated over a larger area, injury could be prevented.



Study

Subjects. The Elder Service Plan is a full-service health care program for frail elders who meet Massachusetts state requirements for nursing home care but desire to remain at home. The mean age of members is 80 years. Members require some assistance with personal care and activities of daily living (ADLs) and have some combination of acute/chronic medical conditions that requires professional monitoring or supervision. The average number of medical conditions is 9.9/member.

Members who were assessed at high risk for falls because they had two or more falls in the previous four months were evaluated for wearing padded underwear to reduce the risk of hip fracture from a fall. This was a non-random assignment of groups but was undertaken in an attempt to immediately reduce the risk of injury in the high fall risk population. Twenty-nine members wore HipSavers during the study and 438 members did not. The two groups were similar along age and sex dimensions. The mean age of the HipSaver population was 79, one year younger than the control population and there were 6 percent more males in the non HipSaver population. The HipSaver population had much higher percentages on measures of history of falls and history of prior hip fractures. Table 1 compares the HipSaver and non HipSaver populations.

Not all 29 test subjects wore HipSavers for the entire 26-month study period. Some developed an increased risk for falls later in the test period and were prescribed HipSavers and their subsequent falls were included in the study group data (Table 2). Members and/or their family/guardian consented to the use of HipSavers as an injury risk reduction intervention.

Method. Falls were recorded on incident report forms. Falls were defined as events resulting in a person inadvertently coming to rest on the ground. Not all falls that occur at home are reported but underreporting skews the data toward serious falls since falls with subsequent consequences are more likely to be reported than falls without injury. Members with a history of falls or high risk factors were evaluated for HipSavers. Incidence of hip fracture in the member population and the HipSaver population were calculated and compared using Fisher's exact test.

Results. The total falls reported were 568 in the 467 members studied over the 26-month period. The 29 members who wore HipSavers accounted for 199 falls or 3.17 falls/member/year. The 438 members who did not wear HipSavers had 369 falls or 0.3888 falls/member/year indicating that the HipSaver group was at nearly eight times higher risk for falls.

Sixteen of the 369 falls among the members not wearing HipSavers resulted in a hip fracture. None of the 199 falls among the members wearing HipSavers resulted in hip fracture. Fisher's exact test analysis comparing falls between the HipSaver and non-HipSaver populations yields a probability of 0.00089576 that this distribution is random. This is less than 0.05 and therefore a highly significant difference (Table 3).

Discussion. Hip fractures in the elderly are devastating, costly, traumatic, life altering and life threatening events. Most hip fractures occur as a result of falls. This has logically led to strategies of risk reduction through fall prevention. "Falls don't just happen. They are predictable occurrences, the outcome of a multitude of host related and environmental factors that are potentially amenable to intervention and thereby reduction or prevention." 12

Despite fall prevention efforts, some patients still experience falls and therefore remain at risk for hip fracture. For some of these patients, HipSavers are an effective injury prevention intervention. This study indicates that shock absorbing hip pads effectively reduced the risk of hip fracture in this Elder Service Plan population. Comparing the cohort of clients wearing HipSavers to those not wearing HipSavers indicates that the experimental group clients are less likely to incur a hip fracture as a result of a fall.

The sample size is small but the results were significant for the Elder Service Plan in implementing a simple, cost effective intervention to reduce hip fractures. The subjects were not randomly assigned but were selected from the same population and prescribed hip pads because of their history and risk of falls. They fell nearly eight times more frequently than the members of the control population. This would seem to make them more likely to sustain a hip fracture but in fact, no hip fractures were sustained by this group, a very promising finding. This study did not include measures of osteoporosis, bone density, nutrition or endocrine factors, which may cause potential differences between the groups likelihood for fracture and this is an area for further study.

Conclusion

Much research has been done on the costs and consequences of hip fractures and the causes of falls. Fall prevention programs are a necessity for any geriatric program. Despite all fall prevention efforts, some

elders continue to fall. Compensatory strategies aimed at reducing the risk of injury from falls is the logical course of action. HipSavers are an effective means of reducing the risk of hip fracture from falls in this population. Despite their effectiveness, HipSavers are not for everyone. Some clients dislike their bulky appearance and choose not to wear them. Some clients, especially those who struggle with ADLs, find that the additional padding makes dressing and toileting more difficult and time consuming. Adaptive clothing might remedy that situation. Patient and/or caregiver acceptance and support is a critical factor since consistent compliance is needed to maximize effectiveness.

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Additional Resource

Adams, R.C. (June 12, 1995). Multiple risk factor intervention successful. ADVANCE for Occupational Therapy, pp.14-15.

George Gross, Tsan-Hui Chen and Carolyn Flaherty are part of the Elder Service Plan Administrative Staff at East Boston Neighborhood Health Center, East Boston, MA.

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8 September 2005

Dear Kay

Please find enclosed the test data you require.

Please remember these are not definitive test data as exactly described in any forthcoming Standards as the position procedure has not been confirmed as the Posey pad appeared to be positioned outside the area of the pad when put on the torso and hence could not be positioned on the rig.

The test results for the Posey and the HipSaver relate to the pad in the garment positioned centrally over the GT stud and hence could be used for comparative purposes only.

I hope that is clear and consequently cannot be referred to test data complying with the impending Standard until the positioning procedure has been clearly defined (This I hope will be determined at the next Standards meeting in October).

Regards

Yours sincerely

Professor Julian Minns Consultant Clinical Scientist

Deposition of Victoria Lewis

Date Accember 15, 2005

For Indentification

Denise Herft, CSR 12983

Case 1:04-cv-11294-PBS Document 36 Filed 09/22/2004 Page 1 of 2

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

STIPULATION FOR DISMISSAL

Plaintiff The HipSaver Company, Inc. and Defendant J.T. Posey Company, Inc., by and through their respective counsel of record, hereby stipulate and agree as follows:

- 1. This entire action shall be and is hereby dismissed with prejudice pursuant to FRCP Rule 41(a)(1)(ii).
- 2. Each party shall bear its own costs, expenses, and attorney's fees.

1

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Case 1:05-cv-10917-PBS Document 183-34 Filed 01/08/2007 Page 3 of 4

IT IS SO STIPULATED.

THE HIPSAVER COMPANY, INC.

J.T. POSEY COMPANY

By its attorneys,

By its attorneys

/s/ Lee Carl Bromberg

Lee Carl Bromberg (BBO No. 058480) Edward J. Dailey (BBO No. 112220) BROMBERG SUNSTEIN, LLP 125 Summer Street, 11th Floor Boston, MA 02110-1618 (617) 443-9292 /s/ Anthony J. Fitzpatrick

Anthony J. Fitzpatrick (BBO No. 564324) DUANE MORRIS LLP 470 Atlantic Avenue, Suite 500 Boston, MA 02210 (617) 289-9200

Jeffrey G. Sheldon William J. Brutocao Shannon S. Sheldon & Mak SHELDON & MAK PC 225 South Lake Avenue, 9th Floor Pasadena, California 91101 (626) 796-4000

September 22, 2004

SO ORDERED:

Patti B. Saris United States District Judge

Date:

Edward Dailey

₹rom:

ECFnotice@mad.uscourts.gov

ent:

Wednesday, September 22, 2004 3:41 PM

To:

CourtCopy@mad.uscourts.gov

Subject:

Activity in Case 1:04-cv-11294-PBS The HipSaver Company, Inc. v. J.T. Posey Company

"Stipulation of Dismissal"

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United States District Court District of Massachusetts

Notice of Electronic Filing

The following transaction was received from Fitzpatrick, Anthony entered on 9/22/2004 at 3:41 PM EDT and filed on 9/22/2004

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Document Number: 36

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Docket Text:

STIPULATION of Dismissal by J.T. Posey Company, The HipSaver Company, Inc.. (Fitzpatrick, Anthony)

The following document(s) are associated with this transaction:

Document description: Main Document

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1:04-cv-11294 Notice will be electronically mailed to:

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2004 HipSaver Website

http://web.archive.org/web/20040612070024/www.hipsaver.com/validation.html

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In this controlled study, the group wearing HipSaver hip protector underwear had a 0% fracture rate (199 falls over 26 months)



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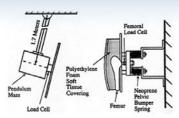
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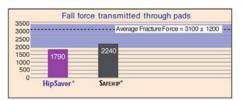
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Biomechanical Testing



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Results show the HipSaver airPadTM, technology reduced the force of impact from 7300 Newtons to 1790 Newtons – that's more than 20% more force reduction than the hard-shell

(Average fracture force: 3100 N +/- 1200 N)

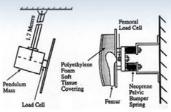
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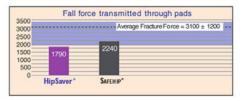
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Why is this important to you?

independent biomechanical testing and clinical validation are crucial for a hip protector. Without them, you won't know IF it works until it HAS to work. And that is too late.

Think of it this way...which parachute would you choose?

One manufactured by a company with proven testing, independent scientific validation and years of market success or one that looks similar but has no performance data or market history.

Don't Settle for Less...

It takes more than foam pads and underwear to provide all-soft hip protection that works! Beware of limitators seeking to cash in on years of HipSaver research, development and testing in materials, processes and actual use.

Only HipSaver products have the unique patent-pending dual-mechanism shunting/absorbing HipSaver® airPad $^{\infty}$ – a system shown to deliver significant impact reduction in independent testing.

In the event of a fall, the HipSaver airPad absorbs impact and inflates the pouch. Acting as a miniature automobile air bag, it shunts force away from the vulnerable hipbone to the soft assue of the buttocks.

HipSavers are the only all-soft hip protectors, proven effective – in both independent biomechanical testing and clinical study.

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Email us at hipsavers@msn.com or call HipSaver toll-free at 1-800-358-4477 for answers to your questions or to discuss any issues.

While HipSaver has achieved excellent and impressive results, no product can claim to be 100% effective all of the time. Therefore HipSaver, Inc. makes no implied or express guarantee that its product will prevent injury.

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http://web.archive.org/web/20040612065616/www.hipsaver.com/thelaundry.html

HIP PROTECTORS & THE LAUNDRY

Only HipSaver hip protectors clearly meets the CDC Guidelines for infection control in the laundry



Hip Savers® wash and dry up to 250° — well above the CDC guidelines.

Posey® Hipsters wash care instructions: Up to a maximum of 160°F (CDC guideline suggested minimum) Dry on low.

Only HipSaver can be laundered according to the CDC (Center for Disease Control) Guidelines for laundry.



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http://web.archive.org/web/20041009151648/www.hipsaver.com/thelaundry.html

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EXHIBIT 29

CONFIDENTIAL, FILED UNDER SEAL

Guidelines for Environmental Infection Control in Health-Care Facilities

Recommendations of CDC and the Healthcare Infection Control **Practices Advisory Committee (HICPAC)**

> U.S. Department of Health and Human Services Centers for Disease Control and Prevention (CDC) Atlanta, GA 30333

> > 2003

EM 0020

PC 1483

Suggested Citations:

Available from the CDC Internet Site:

The full-text version of the guidelines appears as a web-based document at the CDC's Division of Healthcare Quality Promotion's Internet site at: www.cdc.gov/ncidod/hip/enviro/guide.htm

The full-text version of the guidelines should be cited when reference is made primarily to material in Parts I and IV. The print version of the guidelines appears as:

Sehulster LM, Chinn RYW, Arduino MJ, Carpenter J, Donlan R, Ashford D, Besser R, Fields B, McNeil MM, Whitney C, Wong S, Juranek D, Cleveland J. Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Chicago IL; American Society for Healthcare Engineering/American Hospital Association; 2004.

Part II of these guidelines appeared in the CDC's "Morbidity and Mortality Weekly Report:"

Centers for Disease Control and Prevention. Guidelines for environmental infection control in health-care facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR 2003; 52 (No. RR-10): 1–48.

Updates to the Part II recommendations also appeared in the MMWR in 2003 as "Errata: Vol. 52 (No. RR-10)" (MMWR Vol. 52 [42]: 1025-6) on October 24, 2003 and as a "Notice to Readers" scheduled to appear in February 2004. The full-text version of these guidelines (this document) incorporates these updates.

EM 0021

PC 1484

i

Centers for Disease Control and Prevention **Healthcare Infection Control Practices Advisory Committee (HICPAC)**

Guidelines for Environmental Infection Control in **Health-Care Facilities**

Abstract

Background:

Although the environment serves as a reservoir for a variety of microorganisms, it is rarely implicated in disease transmission except in the immunocompromised population. Inadvertent exposures to environmental opportunistic pathogens (e.g., Aspergillus spp. and Legionella spp.) or airborne pathogens (e.g., Mycobacterium tuberculosis and varicella-zoster virus) may result in infections with significant morbidity and/or mortality. Lack of adherence to established standards and guidance (e.g., water quality in dialysis, proper ventilation for specialized care areas such as operating rooms, and proper use of disinfectants) can result in adverse patient outcomes in health-care facilities.

Objective:

The objective is to develop an environmental infection-control guideline that reviews and reaffirms strategies for the prevention of environmentally-mediated infections, particularly among health-care workers and immunocompromised patients. The recommendations are evidence-based whenever possible.

Search Strategies:

The contributors to this guideline reviewed predominantly English-language articles identified from MEDLINE literature searches, bibliographies from published articles, and infection-control textbooks.

Criteria for Selecting Citations and Studies for This Review:

Articles dealing with outbreaks of infection due to environmental opportunistic microorganisms and epidemiological- or laboratory experimental studies were reviewed. Current editions of guidelines and standards from organizations (i.e., American Institute of Architects [AIA], Association for the Advancement of Medical Instrumentation [AAMI], and American Society of Heating, Refrigeration, and Air-Conditioning Engineers [ASHRAE]) were consulted. Relevant regulations from federal agencies (i.e., U.S. Food and Drug Administration [FDA]; U.S. Department of Labor, Occupational Safety and Health Administration [OSHA]; U.S. Environmental Protection Agency [EPA]; and U.S. Department of Justice) were reviewed. Some topics did not have well-designed, prospective studies nor reports of outbreak investigations. Expert opinions and experience were consulted in these instances.

Types of Studies:

Reports of outbreak investigations, epidemiological assessment of outbreak investigations with control strategies, and in vitro environmental studies were assessed. Many of the recommendations are derived

EM 0022

ii

from empiric engineering concepts and reflect industry standards. A few of the infection-control measures proposed cannot be rigorously studied for ethical or logistical reasons.

Outcome Measures:

Infections caused by the microorganisms described in this guideline are rare events, and the effect of these recommendations on infection rates in a facility may not be readily measurable. Therefore, the following steps to measure performance are suggested to evaluate these recommendations:

- 1. Document whether infection-control personnel are actively involved in all phases of a healthcare facility's demolition, construction, and renovation. Activities should include performing a risk assessment of the necessary types of construction barriers, and daily monitoring and documenting of the presence of negative airflow within the construction zone or renovation
- 2. Monitor and document daily the negative airflow in airborne infection isolation rooms (AII) and positive airflow in protective environment rooms (PE), especially when patients are in these
- 3. Perform assays at least once a month by using standard quantitative methods for endotoxin in water used to reprocess hemodialyzers, and for heterotrophic, mesophilic bacteria in water used to prepare dialysate and for hemodialyzer reprocessing.
- 4. Evaluate possible environmental sources (e.g., water, laboratory solutions, or reagents) of specimen contamination when nontuberculous mycobacteria (NTM) of unlikely clinical importance are isolated from clinical cultures. If environmental contamination is found, eliminate the probable mechanisms.
- 5. Document policies to identify and respond to water damage. Such policies should result in either repair and drying of wet structural materials within 72 hours, or removal of the wet material if drying is unlikely within 72 hours.

Main Results:

Infection-control strategies and engineering controls, when consistently implemented, are effective in preventing opportunistic, environmentally-related infections in immunocompromised populations. Adherence to proper use of disinfectants, proper maintenance of medical equipment that uses water (e.g., automated endoscope reprocessors and hydrotherapy equipment), water-quality standards for hemodialysis, and proper ventilation standards for specialized care environments (i.e., airborne infection isolation [AII], protective environment [PE], and operating rooms [ORs]), and prompt management of water intrusion into facility structural elements will minimize health-care-associated infection risks and reduce the frequency of pseudo-outbreaks. Routine environmental sampling is not advised except in the few situations where sampling is directed by epidemiologic principles and results can be applied directly to infection control decisions, and for water quality determinations in hemodialysis.

Reviewers' Conclusions:

Continued compliance with existing environmental infection control measures will decrease the risk of health-care—associated infections among patients, especially the immunocompromised, and health-care workers.

EM 0023

Centers for Disease Control and Prevention Healthcare Infection Control Practices Advisory Committee (HICPAC)

Guidelines for Environmental Infection Control in Health-Care Facilities

Table of Contents

Executive Summary	1
Part I. Background Information: Environmental Infection Control in Health-Care	
Facilities	3
A. Introduction	3
B. Key Terms Used in this Guideline	5
C. Air	
1. Modes of Transmission of Airborne Diseases	
2. Airborne Infectious Diseases in Health-Care Facilities	7
3. Heating, Ventilation, and Air Conditioning Systems in Health-Care Facilities	13
4. Construction, Renovation, Remediation, Repair, and Demolition	21
5. Environmental Infection-Control Measures for Special Health-Care Settings	34
6. Other Aerosol Hazards in Health-Care Facilities	
D. Water	40
1. Modes of Transmission of Waterborne Diseases	
2. Waterborne Infectious Diseases in Health-Care Facilities	
3. Water Systems in Health-Care Facilities	
4. Strategies for Controlling Waterborne Microbial Contamination	
5. Cooling Towers and Evaporative Condensers	
6. Dialysis Water Quality and Dialysate	
7. Ice Machines and Ice	
8. Hydrotherapy Tanks and Pools	67
9. Miscellaneous Medical/Dental Equipment Connected to Main Water Systems	
E. Environmental Services	
1. Principles of Cleaning and Disinfecting Environmental Surfaces	71
2. General Cleaning Strategies for Patient-Care Areas	
3. Cleaning Strategies for Spills of Blood and Body Substances	
4. Carpeting and Cloth Furnishings	
5. Flowers and Plants in Patient-Care Areas	
6. Pest Control	
7. Special Pathogen Concerns	82
F. Environmental Sampling	87
General Principles: Microbiologic Sampling of the Environment	
2. Air Sampling	89
3. Water Sampling	
4. Environmental Surface Sampling	
G. Laundry and Bedding	
1. General Information	9
2. Epidemiology and General Aspects of Infection Control	9
3. Collecting, Transporting, and Sorting Contaminated Textiles and Fabrics	9

4. Parameters of the Laundry Process 10 5. Special Laundry Situations 10 6. Surgical Gowns, Drapes, and Disposable Fabrics 10 7. Antimicrobial-Impregnated Articles and Consumer Items Bearing Antimicrobial Labeling 10 8. Standard Mattresses, Pillows, and Air-Fluidized Beds 10 H. Animals in Health-Care Facilities 10 1. General Information 10 2. Animal-Assisted Activities, Animal-Assisted Therapy, and Resident Animals 10 3. Service Animals 10 4. Animals as Patients in Human Health-Care Facilities 11 5. Research Animals in Health-Care Facilities 11 1. Epidemiology 11 2. Categories of Medical Waste 11 3. Management of Regulated Medical Waste in Health-Care Facilities 11 4. Treatment of Regulated Medical Waste in Health-Care Facilities 11 5. Discharging Blood, Fluids to Sanitary Sewers or Septic Tanks 11 6. Medical Waste and CJD 11 Part II. Recommendations for Environmental Infection Control in Health-Care Facilitie A. Rationale for Recommendations 11 A. Recommendations—Air 11 D. Recommendations—Environmental Sampling 15		
6. Surgical Gowns, Drapes, and Disposable Fabrics		
7. Antimicrobial-Impregnated Articles and Consumer Items Bearing Antimicrobial Labeling 10 8. Standard Mattresses, Pillows, and Air-Fluidized Beds 10 H. Animals in Health-Care Facilities 10 1. General Information 10 2. Animal-Assisted Activities, Animal-Assisted Therapy, and Resident Animals 10 3. Service Animals 10 4. Animals as Patients in Human Health-Care Facilities 11 5. Research Animals in Health-Care Facilities 11 1. Epidemiology 11 2. Categories of Medical Waste 11 3. Management of Regulated Medical Waste in Health-Care Facilities 11 4. Treatment of Regulated Medical Waste 11 5. Discharging Blood, Fluids to Sanitary Sewers or Septic Tanks 11 6. Medical Waste and CJD 11 Part II. Recommendations for Environmental Infection Control in Health-Care Facilities 11 A. Rationale for Recommendations 11 A. Rationale for Recommendations 11 B. Rating Categories 11 C. Recommendations—Water 11 C. Recommendations—Environmental Services 12 E. Recommendations—Environmental Services 12 E. Recommendations—Environmental Sampling 13 G. Recommendations—Laundry and Bedding 13 H. Recommendations—Regulated Medical Waste 14 Part III. References 14 Part III. References 14 Part IV. Appendices 20 Appendix A. Glossary of Terms 22 Appendix A. Glossary of Terms 22 Appendix S. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2 Appendix C. Water 2 Appendix C. Water 2 Appendix C. Water 2		
8. Standard Mattresses, Pillows, and Air-Fluidized Beds 10 H. Animals in Health-Care Facilities 10 1. General Information 10 2. Animal-Assisted Activities, Animal-Assisted Therapy, and Resident Animals 10 3. Service Animals 10 4. Animals as Patients in Human Health-Care Facilities 11 5. Research Animals in Health-Care Facilities 11 1. Regulated Medical Waste 11 1. Epidemiology 11 2. Categories of Medical Waste 11 3. Management of Regulated Medical Waste 11 4. Treatment of Regulated Medical Waste 11 5. Discharging Blood, Fluids to Sanitary Sewers or Septic Tanks 11 6. Medical Waste and CTD 11 Part II. Recommendations for Environmental Infection Control in Health-Care Facilities 11 A. Rationale for Recommendations 11 B. Rating Categories 11 C. Recommendations—Air 11 D. Recommendations—Water 12 E. Recommendations—Environmental Sampling 12 F. Recommendations—Environmental Sampling 12 H. Recommendations—Alar Medical Waste 14 Par		
H. Animals in Health-Care Facilities	and Consumer Items Bearing Antimicrobial Labeling 103	7. Antimicrobial-Impregnate
H. Animals in Health-Care Facilities	r-Fluidized Beds	8. Standard Mattresses, Pillo
1. General Information 10 2. Animal-Assisted Activities, Animal-Assisted Therapy, and Resident Animals 10 3. Service Animals 10 4. Animals as Patients in Human Health-Care Facilities 11 5. Research Animals in Health-Care Facilities 11 I. Epidemiology 11 1. Epidemiology 11 2. Categories of Medical Waste 11 3. Management of Regulated Medical Waste in Health-Care Facilities 11 4. Treatment of Regulated Medical Waste 11 5. Discharging Blood, Fluids to Sanitary Sewers or Septic Tanks 11 6. Medical Waste and CJD 11 Part II. Recommendations for Environmental Infection Control in Health-Care Facilities 11 A. Rationale for Recommendations 11 B. Rating Categories 11 C. Recommendations—Air 11 D. Recommendations—Water 12 E. Recommendations—Environmental Services 12 F. Recommendations—Environmental Sampling 12 G. Recommendations—Animals in Health-Care Facilities 14 I. Recommendations—Animals in Health-Care Facilities 14 I. Recommendations—Onlimals in Health-Care Facilities		
2. Animal-Assisted Activities, Animal-Assisted Therapy, and Resident Animals 10 3. Service Animals 10 4. Animals as Patients in Human Health-Care Facilities 11 5. Research Animals in Health-Care Facilities 11 1. Regulated Medical Waste 11 1. Epidemiology 11 2. Categories of Medical Waste 11 3. Management of Regulated Medical Waste in Health-Care Facilities 11 4. Treatment of Regulated Medical Waste 11 5. Discharging Blood, Fluids to Sanitary Sewers or Septic Tanks 11 6. Medical Waste and CJD 11 Part II. Recommendations for Environmental Infection Control in Health-Care Facilities 11 A. Rationale for Recommendations 11 B. Rating Categories 11 C. Recommendations—Air 11 D. Recommendations—Environmental Services 15 F. Recommendations—Environmental Sampling 15 G. Recommendations—Environmental Sampling 15 H. Recommendations—Animals in Health-Care Facilities 16 H. Recommendations—Animals in Health-Care Facilities 16 H. References 16 Part III. References 20		
3. Service Animals		
4. Animals as Patients in Human Health-Care Facilities		
5. Research Animals in Health-Care Facilities 11 I. Regulated Medical Waste 11 1. Epidemiology 11 2. Categories of Medical Waste 11 3. Management of Regulated Medical Waste in Health-Care Facilities 11 4. Treatment of Regulated Medical Waste 11 5. Discharging Blood, Fluids to Sanitary Sewers or Septic Tanks 11 6. Medical Waste and CJD 11 Part II. Recommendations for Environmental Infection Control in Health-Care Facilities 11 A. Rationale for Recommendations 11 B. Rating Categories 11 C. Recommendations—Air 11 D. Recommendations—Water 12 E. Recommendations—Environmental Services 12 F. Recommendations—Environmental Sampling 15 G. Recommendations—Laundry and Bedding 15 H. Recommendations—Animals in Health-Care Facilities 16 I. Recommendations—Regulated Medical Waste 16 Part IV. Appendices 16 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae		
I. Regulated Medical Waste 11 1. Epidemiology 11 2. Categories of Medical Waste 11 3. Management of Regulated Medical Waste in Health-Care Facilities 11 4. Treatment of Regulated Medical Waste 11 5. Discharging Blood, Fluids to Sanitary Sewers or Septic Tanks 11 6. Medical Waste and CJD 11 Part II. Recommendations for Environmental Infection Control in Health-Care Facilities 11 A. Rationale for Recommendations 11 B. Rating Categories 11 C. Recommendations—Air 11 D. Recommendations—Water 12 E. Recommendations—Environmental Services 12 F. Recommendations—Environmental Sampling 13 G. Recommendations—Laundry and Bedding 15 H. Recommendations—Animals in Health-Care Facilities 14 I. Recommendations—Animals in Health-Care Facilities 14 Part III. References 14 Part IV. Appendices 20 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae <td< th=""><th></th><th>• • • •</th></td<>		• • • •
1. Epidemiology 11 2. Categories of Medical Waste 11 3. Management of Regulated Medical Waste in Health-Care Facilities 11 4. Treatment of Regulated Medical Waste 11 5. Discharging Blood, Fluids to Sanitary Sewers or Septic Tanks 11 6. Medical Waste and CJD 11 Part II. Recommendations for Environmental Infection Control in Health-Care Facilities 11 A. Rationale for Recommendations 11 B. Rating Categories 11 C. Recommendations—Air 11 D. Recommendations—Water 12 E. Recommendations—Environmental Services 12 F. Recommendations—Environmental Sampling 12 G. Recommendations—Laundry and Bedding 12 H. Recommendations—Animals in Health-Care Facilities 14 I. Recommendations—Regulated Medical Waste 14 Part III. References 14 Appendix A. Glossary of Terms 2 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for H		
2. Categories of Medical Waste 11 3. Management of Regulated Medical Waste in Health-Care Facilities 11 4. Treatment of Regulated Medical Waste 11 5. Discharging Blood, Fluids to Sanitary Sewers or Septic Tanks 11 6. Medical Waste and CJD 11 Part II. Recommendations for Environmental Infection Control in Health-Care Facilities 11 A. Rationale for Recommendations 11 B. Rating Categories 11 C. Recommendations—Air 11 D. Recommendations—Water 12 E. Recommendations—Environmental Services 15 F. Recommendations—Environmental Sampling 15 G. Recommendations—Laundry and Bedding 15 H. Recommendations—Animals in Health-Care Facilities 16 I. Recommendations—Animals in Health-Care Facilities 16 I. References 16 Part IV. Appendices 20 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specificatio		
3. Management of Regulated Medical Waste in Health-Care Facilities 11 4. Treatment of Regulated Medical Waste 11 5. Discharging Blood, Fluids to Sanitary Sewers or Septic Tanks 11 6. Medical Waste and CJD 11 Part II. Recommendations for Environmental Infection Control in Health-Care Facilities 11 A. Rationale for Recommendations 11 B. Rating Categories 11 C. Recommendations—Air 11 D. Recommendations—Environmental Services 15 F. Recommendations—Environmental Sampling 15 G. Recommendations—Laundry and Bedding 15 H. Recommendations—Animals in Health-Care Facilities 16 I. Recommendations—Regulated Medical Waste 16 Part III. References 16 Appendix A. Glossary of Terms 20 Appendix B. Air 20 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2		
4. Treatment of Regulated Medical Waste		
5. Discharging Blood, Fluids to Sanitary Sewers or Septic Tanks 11 6. Medical Waste and CJD 11 Part II. Recommendations for Environmental Infection Control in Health-Care Facilities 11 A. Rationale for Recommendations 11 B. Rating Categories 11 C. Recommendations—Air 11 D. Recommendations—Environmental Services 12 F. Recommendations—Environmental Sampling 13 G. Recommendations—Laundry and Bedding 12 H. Recommendations—Animals in Health-Care Facilities 14 I. Recommendations—Regulated Medical Waste 14 Part III. References 14 Part IV. Appendices 20 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2		
6. Medical Waste and CJD	ıste113	 Treatment of Regulated M
6. Medical Waste and CJD	ry Sewers or Septic Tanks116	5. Discharging Blood, Fluid
Part II. Recommendations for Environmental Infection Control in Health-Care Facilities		6. Medical Waste and CJD.
A. Rationale for Recommendations		
A. Rationale for Recommendations 11 B. Rating Categories 11 C. Recommendations—Air 11 D. Recommendations—Environmental Services 12 F. Recommendations—Environmental Sampling 12 G. Recommendations—Laundry and Bedding 12 H. Recommendations—Animals in Health-Care Facilities 14 I. Recommendations—Regulated Medical Waste 14 Part III. References 14 Part IV. Appendices 20 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2 Appendix C. Water 2		**** ·
B. Rating Categories 11 C. Recommendations—Air 11 D. Recommendations—Environmental Services 12 E. Recommendations—Environmental Sampling 13 G. Recommendations—Laundry and Bedding 14 H. Recommendations—Animals in Health-Care Facilities 14 I. Recommendations—Regulated Medical Waste 14 Part III. References 14 Part IV. Appendices 20 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2		***********
C. Recommendations—Air 11 D. Recommendations—Water 12 E. Recommendations—Environmental Services 13 F. Recommendations—Environmental Sampling 13 G. Recommendations—Laundry and Bedding 13 H. Recommendations—Animals in Health-Care Facilities 14 I. Recommendations—Regulated Medical Waste 14 Part III. References 14 Part IV. Appendices 20 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2		
D. Recommendations—Water		
E. Recommendations—Environmental Services F. Recommendations—Environmental Sampling G. Recommendations—Laundry and Bedding H. Recommendations—Animals in Health-Care Facilities I. Recommendations—Regulated Medical Waste Part III. References Part IV. Appendices Appendix A. Glossary of Terms Appendix B. Air 1. Airborne Contaminant Removal 2. Air Sampling for Aerosols Containing Legionellae 3. Calculation of Air Sampling Results 4. Ventilation Specifications for Health-Care Facilities 2. Appendix C. Water 2. Appendix C. Water 2. Appendix C. Water 2. Appendix C. Water 3. Calculation Specifications for Health-Care Facilities 4. Appendix C. Water 4. Appendix C. Water 4. Care Facilities 4. Appendix C. Water 4. Care Facilities 5. Calculation Specifications for Health-Care Facilities 6. Care Facilities 7. Care		
F. Recommendations—Environmental Sampling 13 G. Recommendations—Laundry and Bedding 13 H. Recommendations—Animals in Health-Care Facilities 14 I. Recommendations—Regulated Medical Waste 14 Part III. References 14 Part IV. Appendices 20 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2		
G. Recommendations—Laundry and Bedding 13 H. Recommendations—Animals in Health-Care Facilities 14 I. Recommendations—Regulated Medical Waste 14 Part III. References 14 Part IV. Appendices 20 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2		
H. Recommendations—Animals in Health-Care Facilities 14 I. Recommendations—Regulated Medical Waste 14 Part III. References 14 Part IV. Appendices 20 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2		
I. Recommendations—Regulated Medical Waste 14 Part III. References 14 Part IV. Appendices 20 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2		
Part III. References 14 Part IV. Appendices 20 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2		
Part IV. Appendices 20 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2		
Part IV. Appendices 20 Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2	145	art III. References
Appendix A. Glossary of Terms 20 Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2	201	Part IV. Annendices
Appendix B. Air 2 1. Airborne Contaminant Removal 2 2. Air Sampling for Aerosols Containing Legionellae 2 3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2	201	Amendix A Glossary of Ter
1. Airborne Contaminant Removal	210	Appendix A. Glossary of Tex
2. Air Sampling for Aerosols Containing Legionellae	210	Appendix D. All
3. Calculation of Air Sampling Results 2 4. Ventilation Specifications for Health-Care Facilities 2 Appendix C. Water 2		
4. Ventilation Specifications for Health-Care Facilities	ing degionenae	2. Air Sampling for Aeroso
Appendix C. Water2		
Appendix C. Water		
1. Biofilms		Appendix C. Water
2. Water and Dialysate Sampling Strategies in Dialysis		
3. Water Sampling Strategies and Culture Techniques for Detecting Legionellae		
4. Procedure for Cleaning Cooling Towers and Related Equipment	wers and Related Equipment225	4. Procedure for Cleaning (
5. Maintenance Procedures Used to Decrease Survival and Multiplications of Legionella spp. in	ecrease Survival and Multiplications of Legionella spp. in	5. Maintenance Procedures
Potable-Water Distribution Systems		
Appendix D. Insects and Microorganisms		
Appendix E. Information Resources	220	Appendix E. Information R
Manager of the statement from the second of	h 72	Appendix E. Argos of Futur
Appendix F. Areas of Future Research		ADDUNULA F. ALCAS OLL ULUL

EM 0025

List of Figures, Boxes, and Tables

rigures
Figure 1. Diagram of a ventilation system14
Figure 2. Example of positive-pressure room control for protection from airborne environmental
microbes (PE)
Figure 3. Example of negative-pressure room control for airborne infection isolation (AII)36
Figure 4. Example of airborne infection isolation (AII) room with anteroom and neutral anteroom 37
Figure 5. Diagram of a typical air conditioning (induced draft) cooling tower
Figure 6. Dialysis water treatment system
Boxes
Box 1. Environmental infection control: performance measures
Box 2. Eight criteria for evaluating the strength of evidence for environmental sources of infection4
Box 3. Chain of infection components
Box 4. Suggested members and functions of a multi-disciplinary coordination team for construction,
renovation, repair, and demolition projects
Box 5. Construction design and function considerations for environmental infection control
Box 6. Unresolved issues associated with microbiologic air sampling28
Box 7. Construction/repair projects that require barrier structures
Box 8. Strategy for managing TB patients and preventing airborne transmission in operating rooms39
Box 9. Recovery and remediation measures for water-related emergencies
Box 10. Contingency planning for flooding53
Box 11. Steps in an epidemiologic investigation for legionellosis
Box 12. General steps for cleaning and maintaining ice machines, dispensers, and storage chests 66
Box 13. Preliminary concerns for conducting air sampling
Box 14. Selecting an air sampling device
Box 15. Undertaking environmental-surface sampling95
Box C.1. Potential sampling sites for Legionella spp. in health-care facilities224
Box C.2. Procedures for collecting and processing environmental specimens for Legionella spp225
Tables
Table 1. Clinical and epidemiologic characteristics of aspergillosis
Table 2. Environmental fungal pathogens: entry into and contamination of the health-care facility 8
Table 3. Clinical and epidemiologic characteristics of tuberculosis (TB)
Table 4. Microorganisms associated with airborne transmission
Table 5. Filtration methods
Table 6. Engineered specifications for positive- and negative pressure rooms
Table 7. Ventilation hazards in health-care facilities that may be associated with increased potential of
airborne disease transmission
Table 8 Strategies to reduce dust and moisture intrusion during external demolition and construction 30

EM 0026

	infection-control measures for internal construction and repair projects	
	Summary of ventilation specifications in selected areas of health-care facilities	
Table 11.	Clinical and epidemiologic characteristics of legionellosis/Legionnaires disease	41
	Pseudomonas aeruginosa infections in health-care facilities	
Table 13.	Other gram-negative bacteria associated with water and moist environments	43
	Nontuberculous mycobacteria—environmental vehicles	
Table 15.	Water and point-of-use fixtures as sources and reservoirs of waterborne pathogens	47
Table 16.	Water demand in health-care facilities during water disruption emergencies	50
Table 17.	Additional infection-control measures to prevent exposure of high-risk patients to waterbor	ne
	ogens	
Table 18.	Microbiologic limits for hemodialysis fluids	62
Table 19.	Factors influencing microbial contamination in hemodialysis systems	63
Table 20.	Microorganisms and their sources in ice and ice machines	65
Table 21.	Infections associated with use of hydrotherapy equipment	67
Table 22.	Levels of disinfection by type of microorganism	72
	Air sampling methods and examples of equipment	
Table 24.	Examples of eluents and diluents for environmental-surface sampling	96
	Methods of environmental-surface sampling	
Table 26.	Examples of diseases associated with zoonotic transmission	105
Table 27.	Microorganisms and biologicals identified as select agents	115
Table B.	 Air changes/hour (ACH) and time required for airborne-contaminant removal efficiencies 	of
99%	6 and 99.9%	210
Table B.2	2. Ventilation requirements for areas affecting patient care in hospitals and outpatient facilit	ies
*****		212
Table B.	3. Pressure relationships and ventilation of certain areas of nursing facilities	217
Table B.	4. Filter efficiencies for central ventilation and air conditioning systems in general hospitals	
*****	,	
Table B.:	5. Filter efficiencies for central ventilation and air conditioning systems in outpatient faciliti	es

Table B.	6. Filter efficiencies for central ventilation and air conditioning systems in nursing facilities	
Table B.	7. Filter efficiencies for central ventilation and air conditioning systems in psychiatric hospi	tals
*****		220
Table D	1 Microorganisms isolated from arthropods in health-care settings	228

EM 0027

can help prevent the generation of potentially contaminated lint aerosols in patient-care areas. 967, 1259 Sorting or rinsing contaminated laundry at the location where contamination occurred is prohibited by OSHA. 967 Contaminated textiles and fabrics are placed into bags or other appropriate containment in this location; these bags are then securely tied or otherwise closed to prevent leakage. Single bags of sufficient tensile strength are adequate for containing laundry, but leak-resistant containment is needed if the laundry is wet and capable of soaking through a cloth bag. 1264 Bags containing contaminated laundry must be clearly identified with labels, color-coding, or other methods so that health-care workers handle these items safely, regardless of whether the laundry is transported within the facility or destined for transport to an off-site laundry service.⁹⁶⁷

Typically, contaminated laundry originating in isolation areas of the hospital is segregated and handled with special practices; however, few, if any, cases of health-care-associated infection have been linked to this source. 1265 Single-blinded studies have demonstrated that laundry from isolation areas is no more heavily contaminated with microorganisms than laundry from elsewhere in the hospital. 1266 Therefore, adherence to standard precautions when handling contaminated laundry in isolation areas and minimizing agitation of the contaminated items are considered sufficient to prevent the dispersal of potentially infectious aerosols.6

Contaminated textiles and fabrics in bags can be transported by cart or chute. 1258, 1262 Laundry chutes require proper design, maintenance, and use, because the piston-like action of a laundry bag traveling in the chute can propel airborne microbial contaminants throughout the facility. Laundry chutes should be maintained under negative air pressure to prevent the spread of microorganisms from floor to floor. Loose, contaminated pieces of laundry should not be tossed into chutes, and laundry bags should be closed or otherwise secured to prevent the contents from falling out into the chute. 1270 Health-care facilities should determine the point in the laundry process at which textiles and fabrics should be sorted. Sorting after washing minimizes the exposure of laundry workers to infective material in soiled fabrics, reduces airborne microbial contamination in the laundry area, and helps to prevent potential percutaneous injuries to personnel. 1271 Sorting laundry before washing protects both the machinery and fabrics from hard objects (e.g., needles, syringes, and patients' property) and reduces the potential for recontamination of clean textiles. Sorting laundry before washing also allows for customization of laundry formulas based on the mix of products in the system and types of soils encountered. Additionally, if work flow allows, increasing the amount of segregation by specific product types will usually yield the greatest amount of work efficiency during inspection, folding, and pack-making operations. Protective apparel for the workers and appropriate ventilation can minimize these exposures. Gloves used for the task of sorting laundry should be of sufficient thickness to minimize sharps injuries. 967 Employee safety personnel and industrial hygienists can help to determine the appropriate glove choice.

4. Parameters of the Laundry Process

Fabrics, textiles, and clothing used in health-care settings are disinfected during laundering and generally rendered free of vegetative pathogens (i.e., hygienically clean), but they are not sterile. 1273 Laundering cycles consist of flush, main wash, bleaching, rinsing, and souring. 1274 Cleaned wet textiles, fabrics, and clothing are then dried, pressed as needed, and prepared (e.g., folded and packaged) for distribution back to the facility. Clean linens provided by an off-site laundry must be packaged prior to transport to prevent inadvertent contamination from dust and dirt during loading, delivery, and unloading. Functional packaging of laundry can be achieved in several ways, including a) placing clean linen in a hamper lined with a previously unused liner, which is then closed or covered; b) placing clean linen in a properly cleaned cart and covering the cart with disposable material or a properly cleaned reusable textile material that can be secured to the cart; and c) wrapping individual bundles of clean

EM 0133

textiles in plastic or other suitable material and sealing or taping the bundles.

The antimicrobial action of the laundering process results from a combination of mechanical, thermal, and chemical factors. ^{1271, 1275, 1276} Dilution and agitation in water remove substantial quantities of microorganisms. Soaps and detergents function to suspend soils and also exhibit some microbiocidal properties. Hot water provides an effective means of destroying microorganisms. ¹²⁷⁷ A temperature of at least 160°F (71°C) for a minimum of 25 minutes is commonly recommended for hot-water washing. ² Water of this temperature can be provided by steam jet or separate booster heater. ¹²⁰ The use of chlorine bleach assures an extra margin of safety. ^{1278, 1279} A total available chlorine residual of 50–150 ppm is usually achieved during the bleach cycle. ¹²⁷⁷ Chlorine bleach becomes activated at water temperatures of 135°F–145°F (57.2°C–62.7°C). The last of the series of rinse cycles is the addition of a mild acid (i.e., sour) to neutralize any alkalinity in the water supply, soap, or detergent. The rapid shift in pH from approximately 12 to 5 is an effective means to inactivate some microorganisms. ¹²⁴⁷ Effective removal of residual alkali from fabrics is an important measure in reducing the risk for skin reactions among patients.

Chlorine bleach is an economical, broad-spectrum chemical germicide that enhances the effectiveness of the laundering process. Chlorine bleach is not, however, an appropriate laundry additive for all fabrics. Traditionally, bleach was not recommended for laundering flame-retardant fabrics, linens, and clothing because its use diminished the flame-retardant properties of the treated fabric. 1273 However, some modern-day flame retardant fabrics can now tolerate chlorine bleach. Flame-retardant fabrics, whether topically treated or inherently flame retardant, should be thoroughly rinsed during the rinse cycles, because detergent residues are capable of supporting combustion. Chlorine alternatives (e.g., activated oxygen-based laundry detergents) provide added benefits for fabric and color safety in addition to antimicrobial activity. Studies comparing the antimicrobial potencies of chlorine bleach and oxygen-based bleach are needed. Oxygen-based bleach and detergents used in health-care settings should be registered by EPA to ensure adequate disinfection of laundry. Health-care workers should note the cleaning instructions of textiles, fabrics, drapes, and clothing to identify special laundering requirements and appropriate hygienic cleaning options. 1278

Although hot-water washing is an effective laundry disinfection method, the cost can be substantial. Laundries are typically the largest users of hot water in hospitals. They consume 50%–75% of the total hot water, ¹²⁸⁰ representing an average of 10%–15% of the energy used by a hospital. Several studies have demonstrated that lower water temperatures of 71°F–77°F (22°C–25°C) can reduce microbial contamination when the cycling of the washer, the wash detergent, and the amount of laundry additive are carefully monitored and controlled. ^{1247, 1281–1285} Low-temperature laundry cycles rely heavily on the presence of chlorine- or oxygen-activated bleach to reduce the levels of microbial contamination. The selection of hot- or cold-water laundry cycles may be dictated by state health-care facility licensing standards or by other regulation. Regardless of whether hot or cold water is used for washing, the temperatures reached in drying and especially during ironing provide additional significant microbiocidal action. ¹²⁴⁷ Dryer temperatures and cycle times are dictated by the materials in the fabrics. Man-made fibers (i.e., polyester and polyester blends) require shorter times and lower temperatures.

After washing, cleaned and dried textiles, fabrics, and clothing are pressed, folded, and packaged for transport, distribution, and storage by methods that ensure their cleanliness until use. State regulations and/or accrediting standards may dictate the procedures for this activity. Clean/sterile and contaminated textiles should be transported from the laundry to the health-care facility in vehicles (e.g., trucks, vans, and carts) that allow for separation of clean/sterile and contaminated items. Clean/sterile textiles and contaminated textiles may be transported in the same vehicle, provided that the use of physical barriers and/or space separation can be verified to be effective in protecting the clean/sterile items from

EM 0134

contamination. Clean, uncovered/unwrapped textiles stored in a clean location for short periods of time (e.g., uncovered and used within a few hours) have not been demonstrated to contribute to increased levels of health-care-acquired infection. Such textiles can be stored in convenient places for use during the provision of care, provided that the textiles can be maintained dry and free from soil and bodysubstance contamination.

In the absence of microbiologic standards for laundered textiles, no rationale exists for routine microbiologic sampling of cleaned health-care textiles and fabrics. 1286 Sampling may be used as part of an outbreak investigation if epidemiologic evidence suggests that textiles, fabrics, or clothing are a suspected vehicle for disease transmission. Sampling techniques include aseptically macerating the fabric into pieces and adding these to broth media or using contact plates (RODAC plates) for direct surface sampling. 1271, 1286 When evaluating the disinfecting properties of the laundering process specifically, placing pieces of fabric between two membrane filters may help to minimize the contribution of the physical removal of microorganisms. 1287

Washing machines and dryers in residential-care settings are more likely to be consumer items rather than the commercial, heavy-duty, large volume units typically found in hospitals and other institutional health-care settings. Although all washing machines and dryers in health-care settings must be properly maintained for performance according to the manufacturer's instructions, questions have been raised about the need to disinfect washers and dryers in residential-care settings. Disinfection of the tubs and tumblers of these machines is unnecessary when proper laundry procedures are followed; these procedures involve a) the physical removal of bulk solids (e.g., feces) before the wash/dry cycle and b) proper use of temperature, detergent, and laundry additives. Infection has not been linked to laundry procedures in residential-care facilities, even when consumer versions of detergents and laundry additives are used.

5. Special Laundry Situations

Some textile items (e.g., surgical drapes and reusable gowns) must be sterilized before use and therefore require steam autoclaving after laundering.⁷ Although the American Academy of Pediatrics in previous guidelines recommended autoclaving for linens in neonatal intensive care units (NICUs), studies on the microbial quality of routinely cleaned NICU linen have not identified any increased risk for infection among the neonates receiving care. 1288 Consequently, hygienically clean linens are suitable for use in this setting. 997 The use of sterile linens in burn therapy units remains unresolved.

Coated or laminated fabrics are often used in the manufacture of PPE. When these items become contaminated with blood or other body substances, the manufacturer's instructions for decontamination and cleaning take into account the compatibility of the rubber backing with the chemical germicides or detergents used in the process. The directions for decontaminating these items should be followed as indicated; the item should be discarded when the backing develops surface cracks.

Dry cleaning, a cleaning process that utilizes organic solvents (e.g., perchloroethylene) for soil removal, is an alternative means of cleaning fabrics that might be damaged in conventional laundering and detergent washing. Several studies, however, have shown that dry cleaning alone is relatively ineffective in reducing the numbers of bacteria and viruses on contaminated linens; 1289, 1290 microbial populations are significantly reduced only when dry-cleaned articles are heat pressed. Dry cleaning should therefore not be considered a routine option for health-care facility laundry and should be reserved for those circumstances in which fabrics can not be safely cleaned with water and detergent. 1291

EM 0135

EXHIBIT 31

CONFIDENTIAL, FILED UNDER SEAL

Exhibit 32

1	IN THE UNITED STATES DISTRICT COURT
2	FOR THE DISTRICT OF MASSACHUSETTS
3	
4	
5	THE HIPSAVER COMPANY, INC., Plaintiff
6	VS. NO. CV 05 10917 PBS
7	
8	J. T. POSEY, Defendant
9	AND RELATED COUNTERCLAIM.
10	
11	
12	DEPOSITION of JEFFREY B. BURL, M. D.,
13	taken at the request of the defendant pursuant
14	to Rule 30 of the Federal Rules of Civil
15	Procedure before Nancy A. Diemdowicz,
16	Registered Merit Reporter, a notary public in
17	and for the Commonwealth of Massachusetts, on
18	August 25, 2005, commencing at 7:35 A.M. at
19	the Fallon Clinic, 630 Plantation Street,
20	Worcester, Massachusetts.
21	
22	
23	
24	

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2
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13
 1
     as -- let's go off the record for just one
 2
     second.
 3
                 (Off-the-record discussion.)
                 MR. MORSEBURG: Can we have this
 4
 5
     marked as Exhibit 1.
 6
 7
             (Deposition Exhibit No. 1 marked.)
 8
           Q.
                 Would you take a look at Exhibit 1,
 9
     please?
               Have you ever seen it before?
10
           Α.
                 I have.
11
           0.
                 What is it?
12
                 It's a published article on the hip
           Α.
13
     protector compliance done in one nursing
     facility.
14
15
           Q.
                 Were you the principal author of
     the -- of the article?
16
17
           Α.
                 Yes.
18
           0.
                 What does the term "statistically
     significant" mean to you?
19
20
           Α.
                 It's a mathematical designation
     indicating that the differences noted between
21
     an experimental and a control group have
22
23
     reached a therapeutic -- therapeutic window
     demonstrating effectiveness.
24
```

Q. As I understand the report, it's
basically a report of the study, and the
purpose of the study was to determine whether
residents in long-term health care facilities
could be I don't want to say convinced, but
could be brought to wear hip protectors among
people who are at risk for, say, falling and
maybe suffering a hip fracture. Is that
approximately right?
A. That's correct.
Q. Okay. In the report, it says that
you used a particular brand of hip protector
called HipSavers; is that right?
A. Correct.
Q. What was the reason for picking
HipSavers as the product to use among the
subjects in the study?
A. We had contacted several
organizations that were using hip protectors.
One organization in Boston, the Pace Program,
had been utilizing HipSavers for the past two
years.

They were very satisfied with the

HipSavers' service and delivery and

		<i>a</i> =			
1	willingness to come out to the facility for	15			
2	instructions on measuring, for example.				
3	So we contacted HipSavers, asking				
4	them if they'd be willing to provide the same				
5	service to us both for the study as well as				
6	for, you know, subsequent use, and they				
7	agreed.				
8	Q. Is it fair to say that HipSaver was				
9	not picked as a result of any preference of				
10	quality for one brand of hip protector over				
11	another?				
12	A. The choice of HipSavers was based				
13	on the proximity to the study site and their				
14	service reputation.				
15	Q. Prior to have you ever spoken				
16	with an individual named Edward Goodwin?				
17	A. I had.				
18	Q. When's the last time you spoke with				
19	him?				
20	A. Two years ago.				
21	Q. Can you tell from the report what				
22	the compliance rate was overall among the				
23	well, let me just withdraw that.				
24	The report talks about the results				

30 7 COMMONWEALTH OF MASSACHUSETTS 2 WORCESTER, SS. 3 I, NANCY A. DIEMDOWICZ, a notary public in 4 and for the Commonwealth of Massachusetts, do certify that pursuant to appropriate notice of 5 6 taking deposition, there came before me the subject deponent, who was by me duly sworn; 7 8 that said witness was thereupon examined under 9 oath and said examination reduced to writing 10 by me; and that the deposition is a true 11 record of the testimony given by the witness. 12 I further certify that I am not a relative 13 or employee or counsel or attorney for any of 14 the parties, or a relative or employee of such 15 counsel or attorney, nor am I financially or 16 otherwise interested in the outcome of the 17 action. 18 Witness my hand and official seal at 19 Worcester, Massachusetts, this 29th day of CERTIFIED TRANSCRIPT 20 August, 2005. LEGALINKBOSTON 21 My Commission Expires 22 September 20, 2007 23 The foregoing certification of this transcript does not apply to any reproduction 24 of the same in any respect unless under the direct control of the certifying reporter.

I have read the foregoing, and it is a true transcript of the testimony given by me at the taking of the subject deposition. JEFFREY B. BURL, M. D. DATE ND

1	ERRATA SHEET	32
2	I WISH TO MAKE THE FOLLOWING	
3	CHANGES IN THE FOREGOING TRANSCRIPT OF MY	
4	DEPOSITION:	
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6	PAGE LINE CHANGE REASON	
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	ND JEFFREY B. BURL, M. D.	
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Exhibit 33

Interpretation of Biomechanical Testing of HipSaver® Dual-mechanism Shunting/Absorbing AirPad

August 2000

Background: HipSaver pads were tested at the Harvard affiliated laboratory in 1996 and found to offer 10% better impact attenuation than SafeHip® (SafeHip is the product resulting from the initial research efforts as reported in *The Lancet* 1993 341:11-18). Since then HipSaver has researched a variety of materials with various attributes for potential incorporation into the HipSaver product. In August 2000, the selected construction (HSPE4 12.7mm) was sent to the Tampere University of Technology Applied Mechanics Laboratory for impact testing on a mechanical hip system. The research group affiliated with this laboratory is currently most active in the development and biomechanical testing of hip protectors and has several published reports on the subject.

HipSaver Pad Construction: HipSaver encloses a ½" (12.7mm) thick damping foam material in a waterproof/air tight pouch. The pads taper down to 1mm at the edge. The pouch is either RF or heat sealed around the perimeter. Pad diameters are 6.5 to 7.5 inches. These pads are sewn into polycotton underwear so as to overlie the trochanters.

Test Results: The test system and protocol are identical to that reported in *Bone* 1999 Aug. 25(2):229-35 (abstract enclosed). The pad being tested is affixed to a surrogate hip bone and then impacted by a swinging pendulum. Load cells capture the amount of force on the system. The test report on HipSaver shows the HipSaver pad (HSPE4 12.7mm) lowered a typical falling force of 7200N to below the fracture threshold of 3100N +/- 1200N. The following table compares the results from the HipSaver test to other pads tested in the *Bone* report (using the identical system and protocol):

Pad Id.	Description	7200N Fall Force Reduced to
KPH2	35mm height, polyethylene shell	760N
SafeHip	25mm height, polypropylene shell	2240N
Saftypants	20mm thick, low density polyethylene (soft)	2270N
HipSaver HSPE4	12.7mm thick, urethane foam in pouch (soft)) 1790N

Conclusion: Only KPH2 and HipSaver reduced the applied force clearly below the fracture threshold of 3100N (+/- 1200N). A lower value on this test indicates better protective capacity since the values represent force REDUCTION. The above shows HipSaver to offer 20% more attenuation than Safehip.

The Damping Foam Absorbs the Shock and the Displaced Air Redistributes the Forces in the AirPad:

Although the HipSaver pad has the lowest profile (thinness) and is the softest, it performed remarkably well when compared to the stiffer and thicker pads. This result stems from the fact that the airtight pouch renders an "energy shunting" or diverting effect on the applied force: the initial impact is absorbed by the urethane foam and the displaced air from the foam inflates or distends the surrounding pouch. Hence, much similar to automotive air bag, the force is redistributed over a larger and softer area. This inflation effect can be demonstrated by pushing a HipSaver pad with the heel of the hand and observing the distention of the pouch. The HipSaver pad is thus a dual mechanism "shunting/absorbing" air pad.

For more information on HipSaver contact: Ed Goodwin, tel: 781-828-3880 e-mail: hipsavers@msn.com URL www.hipsaver.com





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Trochanteric pad tests HipSaver®

Two thicknesses of the hip protector type HSPE4 were tested. The thickness of the thinner model was 8.4 mm, the thicker one was 12.7 mm. These pads were enclosed in waterproof nylon and polycotton knit material. These pad tests were performed at the midrange force of 7230 N as per the protocol and the testing system described in *Bone* 1999 Aug. 25(2):229-35. The above-mentioned force was attenuated by soft tissue to the value of 5600 N, which match the average peak hip impact force measured in the muscle-relaxed state during in vitro falling tests (Robinovitch et al. 1991). Pad named PE30 (thickness 20 mm) was used to simulate the soft tissue and that pad was changed after every impact for a new one. Six impact tests were done for every pad type. Then the force measurements were filtered and evaluations of averaged peak values and standard deviations were calculated to get the maximum compressive impact forces as seen in Table 1. Typical time-dependent test curves of both thicknesses are seen in Figure 2.

Table 1 Averaged trochanteric impact forces and their standard deviations.

Speed	Energy	HSPE4		HSPE/	
		8.4 mm		12.7 mm	
1.9	74	Mean	Std	Mean	Std
m/s	Nm ·	kN	kN	kN	kN
		2.51	0.071	1.79	0.067

Discription of facilities and the calibration

The data acquisition system is based on Microstar Laboratories Data Acquisition Processor DAP 3200A. The DAP 3200A has the DAPL operating system.

The acquired data were analyzed by Matlab, which is used to numeric computation and visualization. The Matlab is a trademark of the Math Works.

The sampling time was $10 \, \mu s$. The number of acquired points was $1500 \, \text{for each test}$ curve.

Known pads were used to see the same impact force level as reached in the tests earlier. The test system is seen in Figure 1.

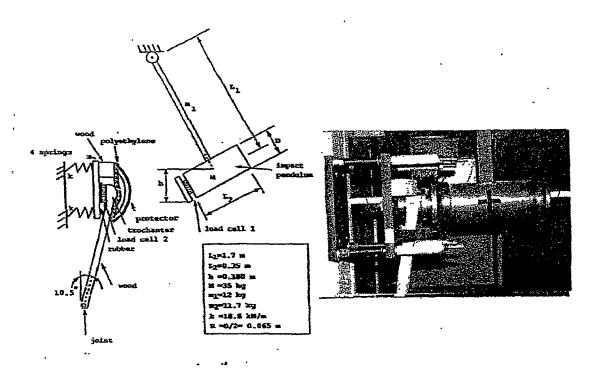


Figure 1 The hip protector testing system.

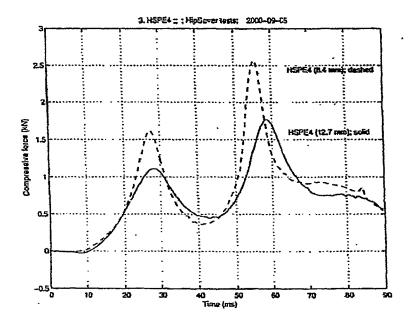


Figure 2 Test curves for the third impact of HSPE4 of the both thicknesses.

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